OMB No. 0990-0115

# Electronic Request for Proposal

## SECTION A – SOLICITATION/CONTRACT FORM

**OFFERORS ARE RESPONSIBLE FOR ROUTINELY CHECKING THE CMB WEBSITE http://www.niaid.nih.gov/contract/default.htm FOR ANY POSSIBLE SOLICITATION AMENDMENTS THAT MAY BE ISSUED. NO ADDITIONAL NOTIFICATION OF ANY AMENDMENTS WILL BE PROVIDED BY THIS OFFICE.**

**Purchase Authority: Public Law 92-218, as amended.**
**NOTE: The issuance of this solicitation does not commit the government to an award.**

| ***RFP Number:*** | ***Just In Time:*** | ***Small Bus. Set-Aside*** [ ]Yes [X]No<br>8(a) Set-Aside [ ]Yes [X]No<br>NAICS Code: 54171<br>Size Standard: 500 employees | ***Level of Effort:***<br>[ ] Yes [X] No<br>***Total Effort:***<br>[ N/A ] |
|---|---|---|---|
| NIH-NIAID-DAIT-02-23 | [ ] Yes<br>[X] No | | |

***TITLE:*** **Statistical and Clinical Coordinating Center for Autoimmune Disease Clinical Trials (SACCC-ADCT)**

| ***Issue Date:*** **01/04/2002** | ***Due Date:*** **03/18/2002**<br>***Time:*** **3:00 PM, EST** | ***Technical Proposal Page Limits:***<br>[ X] Yes *(see "How to Prepare and Submit Electronic Proposals")*<br>[ ] No |
|---|---|---|

***ISSUED BY:***
Barbara A. Shadrick
Senior Contracting Officer
NIH, NIAID, DEA, CMB
6700-B Rockledge Drive
Room 2230, MSC 7612
Bethesda, MD 20892-7612

[X] ***We reserve the right to make awards without discussion.***

| ***NO. OF AWARDS:*** | ***PERIOD OF PERFORMANCE:*** |
|---|---|
| [X] Only 1 Award<br>[ ] Multiple Awards | 7 years beginning on or about 09/15/2002 |

Offers will be valid for 120 days unless a different period is specified by the Offeror on the form entitled "Proposal Summary and Data Record, NIH-2043" (See SECTION J - Attachments)

The Official Point of Receipt for the purpose of determining timely delivery is the Contract Management Branch as stated above. The paper copy with original signatures is the official copy for recording timely receipt. If the paper copy of your proposal is not received by the Contracting Officer or Designee at the place and time specified, then it will be considered late and handled in accordance with HHSAR 352.215-70 entitled "Late Proposals and Revisions" located in this Solicitation.

**FACSIMILE SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE.**

***POINT OF CONTACT*** **-- Scott Drega** ***--COLLECT CALLS WILL NOT BE ACCEPTED--***

| ***Telephone: Direct*** **301-496-6424** | ***Main Office:*** **301-496-0612** | ***E-Mail :*** Sdrega@niaid.niih.gov |
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Updated thru FAC 2001-01 (eff. 12/18/01)

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## BACKGROUND / STATEMENT OF WORK / NOTES TO OFFERORS

### Background

Statistical and Clinical Coordinating Center for Autoimmune Disease Clinical Trials (SACCC- ADCT)
DAIT-02-23

## INTRODUCTION

To address the present needs of the Government, the Division of Allergy, Immunology and Transplantation, National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health, is requesting proposals to establish and manage a Statistical and Clinical Coordinating Center to provide support for the Autoimmunity Centers of Excellence and the Autoimmune Diseases Transplantation Consortium, hereinafter referred to as the ACEs and the Consortium. These programs design and conduct clinical trials to evaluate the safety, toxicity and efficacy of 1) immunomodulatory and tolerogenic approaches to the treatment and prevention of autoimmune diseases and 2) stem cell transplantation for the treatment of multiple autoimmune diseases, respectively. Both programs also support the design and conduct of studies of the underlying mechanisms of these therapeutic approaches as an integral part of the clinical trials undertaken.

The purpose of this seven (7)-year contract is to: (1) provide statistical leadership and clinical trial design expertise for the development, implementation and analysis of clinical trials and studies of underlying mechanisms; (2) establish and administer a reliable, efficient and responsive system for the collection, storage, management, quality assurance and reporting of study data, including systems of patient registration and randomization for clinical trials; (3) conduct clinical site monitoring and training in protocol implementation, as well as data collection, management, quality control and reporting requirements; (4) provide support for regulatory and technical functions and requirements associated with Investigational New Drug (IND) Applications and Investigational Device Exemption applications (IDEs), including adverse event reporting; (5) prepare interim and final analyses of study data, including reports and analyses for review by an independent NIAID Data and Safety Monitoring Board; (6) coordinate and provide support of technical and administrative activities of the ACE Steering Committee, the Consortium Operations/Study Teams, and an NIAID Data and Safety Monitoring Board; and (7) provide for the distribution of study products if needed.

## BACKGROUND

The NIAID Division of Allergy, Immunology and Transplantation (DAIT) promotes and supports a broad range of research aimed at elucidating the immune mechanisms underlying autoimmune diseases and translating this basic knowledge to clinical applications that will benefit individuals affected by these diseases. The ultimate goal of this research program is the development of effective approaches for the treatment and prevention of autoimmune diseases.

### Autoimmunity Centers of Excellence

The Autoimmunity Centers of Excellence, a cooperative research program established in 1999, are an integrated network of centers to carry out a multidisciplinary program of basic, pre-clinical and clinical research focused on tolerance induction and immune modulation to treat and prevent autoimmune disease. Each Center includes a clinical component, incorporating multiple clinical specialists, which conducts pilot clinical trials of the safety, toxicity and potential efficacy of promising tolerogenic and immunomodulatory therapies for multiple autoimmune diseases, and conducts studies of the mechanisms of action of tolerogenic and immunomodulatory interventions. Each Center also includes two or more basic and/or pre-clinical research components focused on elucidation of the basic mechanisms of autoimmunity, self tolerance and/or immune modulation.

Overall scientific leadership and direction for the Autoimmunity Centers of Excellence is carried out by a Steering Committee, composed of Center basic and clinical investigators, NIAID scientific staff, and the Project Director for the Statistical and Clinical Coordinating Center (APPENDIX A). The ACE Steering Committee is responsible for: (1) the development and ongoing review and modification of the scientific agenda; (2) the establishment and implementation of procedures for the development, review and evaluation of concepts for clinical trials and mechanistic studies, including evaluation/selection criteria to be used; (3) setting priorities among proposed concepts; (4) monitoring and evaluating progress; (5) allocating resources; and (6) assessing the need for redirection in scientific focus and implementing necessary changes to redirect resources in order to accommodate new knowledge and changing opportunities.

Currently, the ACEs are supporting three open trials. A phase 1 study of anti-CD20 antibody for the treatment of systemic lupus erythematosus, a multi-site trial of anti-C5 for the treatment of lupus nephritis, and a placebo controlled double masked trial of glatiramer acetate with salbutamol for the treatment of early multiple sclerosis. Several other trials are in development.

**Stem Cell Transplantation for Autoimmune Diseases Consortium**

Early evidence of the efficacy of stem cell transplantation (immune ablation and stem cell support) for autoimmune disease came from isolated reports of dramatic improvements of coincident autoimmune diseases in patients treated with allogeneic stem cell transplants for cancer. Although short-term small pilot trials suggest that this procedure is safe and have shown clinical improvement in certain highly selected patients with several autoimmune diseases, immune ablation with autologous stem cell transplantation is not without significant risks. Mortality from autologous stem cell transplantation ranges from 1-10% in patients with cancer and leukemia. Recently, the depletion of T cells from autologous peripheral blood stem cells using CD34+ selection has produced the most promising results in safety and clinical response.

The mechanism underlying the remission of autoimmune disease in patients after immune ablation and stem cell infusion is unclear. Regeneration of the immune system may result in the generation of self-tolerance through exposure of lymphocyte precursors to self-antigens early in re-development of the immune system. Another possibility is a shift in immune regulatory cells such that autoreactive cells are down regulated. Evidence that a combination of genetic susceptibility and environmental insult are necessary for the development of most autoimmune diseases suggests that ablation and regeneration of the immune system may result in unresponsiveness to self until re-exposure to a disease-inducing agent. To further elucidate the basic mechanisms, studies of immune regeneration and the autoimmune responses in patients who have received stem cell transplants are needed.

Clinical trials and studies are now ongoing at many transplant centers in Europe and the United States. However, the interpretation of the results of these studies is complicated by differences in patient selection criteria, conditioning regimens, methods of stem cell preparation, outcome measures, and length of follow-up. To address the need for cooperative and collaborative safety and efficacy studies of stem cell transplantation for autoimmune diseases, NIAID established the Stem Cell Transplantation for Autoimmune Diseases Consortium, which is supported by three separate contracts. The investigators on these contracts are working together in Study Teams to design and implement multiple clinical trials, including mechanistic studies, of this approach for the treatment of multiple autoimmune diseases. An Operations Committee composed of the principal investigators of the three contracts, representatives from each Study Team, NIAID scientific staff, and the Principal Investigator for the Statistical and Clinical Coordinating Center, will provide scientific leadership and direction for the overall governance of the of the Stem Cell Transplantation in Autoimmune Diseases Consortium. The Operations Committee and the Study Teams will meet twice annually for a period of 5 years in Bethesda, Maryland area and will conduct conference calls as needed. The current investigators in the Stem Cell Transplantation in Autoimmune Diseases Consortium are listed in APPENDIX B.

This solicitation encompasses the establishment of the Statistical and Clinical Coordinating Center and the provision of statistical, clinical coordination, technical, regulatory, and administrative support for: clinical trials undertaken by the Autoimmunity Centers of Excellence (ACEs) for evaluating the safety and efficacy of promising immunomodulatory and tolerogenic agents for the prevention and treatment of autoimmune diseases and by the Autoimmune Diseases Transplantation Consortium (Consortium) for evaluation of the safety and efficacy of stem cell transplantation approaches for treatment of autoimmune diseases; and investigations of the underlying mechanisms of such therapeutic agents and approaches.

The purpose of this RFP is to solicit proposals to provide the statistical, clinical coordination, regulatory, technical and administrative support necessary for the design, conduct, monitoring and evaluation of clinical trials and mechanistic studies to be carried out by the Stem Cell Transplantation in Autoimmune Diseases Consortium. The Statistical and Clinical Coordinating Center shall provide support for the Consortium for a total period of seven (7) years.

Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, materials, equipment, and facilities, not otherwise provided by the Government under the terms of this contract, as needed to perform the work set forth below.

1. **Establish and manage the Statistical and Clinical Coordinating Center (SACCC) for the Autoimmunity Centers of Excellence and the Autoimmune Diseases Transplantation Consortium (hereinafter referred to as the ACEs and the Consortium)**. The Contractor shall provide the statistical, clinical, technical, regulatory and administrative expertise necessary to carry out the tasks specified below, and other tasks as directed by the Project Officer:

    a) Provide statistical leadership for the design and analysis of clinical trials and studies of underlying mechanisms conducted by the ACEs and the Consortium;

    b) Provide clinical trial expertise for the design, implementation, refinement, modification and monitoring of clinical trials and studies of underlying mechanisms conducted by the ACEs and the Consortium;

    c) Design and conduct interim and final analyses of study data;

    d) Conduct clinical site monitoring and training;

    e) Establish and administer data collection, management, quality assurance and reporting systems;

    f) Provide support for regulatory functions and requirements associated with Investigational New Drug (IND) applications and with Investigational Device Exemption (IDE) applications;

    g) Distribute and ensure quality control of study products;

    h) Support the technical and administrative functions of the ACEs Steering Committee and the Consortium Operations Committee and Study Teams; and

    i) Coordinate, provide administrative support, and prepare reports and statistical analyses for the activities of independent Data and Safety Monitoring Boards (DSMBs).

*[SEE NOTE TO OFFEROR: #1]*

2. **Provide statistical leadership and clinical trial design expertise for the development of proposals for clinical trials**, designed either to test the safety and/or efficacy of immunomodulatory or tolerogenic approaches to prevent or treat an autoimmune disease or to test the safety and/or efficacy of use of stem cell transplantation to treat an autoimmune disease to be conducted by the ACEs or the Consortium. Clinical trial design expertise shall include appropriate autoimmune disease specific and stem cell transplantation specific medical expertise. Statistical leadership and clinical trial design expertise shall be used to assist investigators to develop their proposals, from concepts for clinical trials to detailed clinical protocols, with respect to:

    a) Delineation of the research questions to be addressed;

    b) Selection of appropriate study populations and control or comparison groups;

    c) Development of inclusion and exclusion criteria;

    d) Calculation of sample size requirements for statistical significance for clinical trials;

    e) Definition of clinical end-points and immune/surrogate markers;

    f) Selection of randomization and stratification methods;

g) Definition of the number and type of patient biological samples and proposed methods for their collection;

h) Assessment of the feasibility of recruiting and retaining adequate numbers of study participants;

i) Design and development of study forms in collaboration with ACEs and Consortium investigators; and

j) Preparation and updating, as necessary, of a Manual of Operations for each clinical protocol delineating specific instructions, requirements and guidelines for the conduct of clinical trials by the clinical sites, including the clinical protocol, study forms, procedures for the collection, testing, storage and shipping of patient samples, and procedures for data collection, entry, verification and storage.

Proposals for clinical trials may be initiated as brief summaries ("concepts"). Once the Project Officer and the ACE Steering Committee or Consortium Operations Committee approves a concept for development, the SACCC Contractor shall provide statistical and clinical trial design assistance to the investigators in the development of the proposed concept into a full proposal for a clinical trial. In addition, the Contractor shall assign a senior statistician and other appropriate SACCC staff to each concept approved for protocol development. SACCC staff shall have responsibility for working with Consortium investigators and NIAID staff to develop clinical protocols, including:

k) Participating extensively in the writing of proposed concepts and draft clinical protocols;

l) Arranging conference calls and meetings to review and modify, as necessary, proposed concepts and detailed clinical protocols, including all costs associated with conference calls and travel expenses for SACCC staff, ACE or Consortium investigators to attend concept development and protocol development meetings as necessary;

m) Distributing proposed concepts and clinical protocols to members of the ACEs Steering Committee or the Consortium Operations Committee or Study Teams for evaluation; and

n) Preparing and distributing final approved concepts and clinical protocols to the Consortium Operations Committee and all participating clinical sites.

*[SEE NOTES TO OFFEROR: #2, #3]*

3. **Provide statistical leadership and clinical trial design expertise for the development of proposals for mechanistic studies to be carried out by the ACEs and the Consortium** to elucidate the underlying mechanisms of the tested approaches or agent(s) in treatment or prevention of autoimmune disease.

   Proposals for mechanistic studies may be initiated as brief summaries ("concepts"). Once a concept is approved for development into a full proposal for a mechanistic study by the Project Officer and the ACEs Steering Committee or the Consortium Operations Committee, the SACCC Contractor shall assist investigators in the development of proposals for mechanistic studies, integration of these studies into clinical trials, and detailed research plans for all such studies, including:

   a) Delineation of the research questions to be addressed;

   b) Statistical parameters associated with the techniques and methodologies to be used to assess underlying mechanisms;

   c) The type, number and volume of patient samples required and specific instructions to clinical sites for the appropriate collection, testing, storage and shipping of patient samples;

   d) The analysis of new techniques and methodologies in comparison with standard approaches to the measurement of disease stage, activity and clinical outcome; and

   e) The design and development of assay-specific study forms in collaboration with ACE or Consortium Investigators.

   In addition, the Contractor shall assign a senior statistician and other appropriate SACCC staff to each concept approved for implementation. SACCC staff shall have responsibility for working with Consortium investigators and NIAID staff in developing research designs for mechanistic studies, including:

f) Assisting ACE and Consortium investigators in the writing of proposals and draft research designs;

g) Arranging conference calls and meetings to review and modify, as necessary, proposed concepts and detailed research designs, including the costs associated with conference calls and meeting travel expenses for SACCC staff and ACE or Consortium investigators, as necessary;

h) Distributing proposed concepts and research designs to members of the ACE Steering Committee or Consortium Operations Committee for evaluation; and

i) Preparing and distributing final approved proposals and research designs to the ACE Steering Committee or Consortium Operations Committee and all participating clinical sites and mechanistic study sites.

*[SEE NOTES TO OFFEROR: #4, #5]*

4. As directed by the Project Officer, and in collaboration with ACE investigators and Consortium investigators, **design and conduct interim and final statistical analyses of study data, prepare reports on the status of clinical trials and mechanistic studies, and participate in the preparation of scientific manuscripts and reports for publication and presentation at scientific meetings**. This shall include, but not be limited to:

   a) Preparing interim and final analyses of: the safety and efficacy of treatments evaluated in the ACE and Consortium clinical trials; and the validity, reliability and specificity of techniques and methodologies used to assess underlying mechanisms and to study biomarkers;

   b) Developing recommendations for modifications in the design of ongoing clinical trials and mechanistic studies with respect to statistical parameters such as sample size, control or comparison groups, clinical endpoints and immune/surrogate markers, and other relevant parameters;

   c) Preparing interim reports on accrual, retention, compliance, loss to follow-up and other statistical issues and problems relevant to the conduct of ACE and Consortium clinical trials, and recommendations for improvements and modifications to resolve such issues and problems; and

   d) Presenting all such reports, analyses and recommendations to the NIAID and the ACE Steering Committee or Consortium Operations Committee or appropriate Consortium Study Team, and assisting in implementing necessary modifications approved by this governing body, including revised clinical protocols and research designs for mechanistic studies.

5. **Establish and administer efficient, reliable and responsive systems for the collection, storage, management, quality assurance and reporting of study data, as well as a system for electronic communication linkages** (e.g., secure web-site with "chat capabilities" or list-serve) among ACE or Consortium clinical and mechanistic study sites, the NIAID, and the appropriate Steering or Operations Committee. The Contractor shall develop and manage systems that provide for:

   a) The collection, computer processing, storage, tracking and retrieval of all clinical and laboratory study data at a central data management facility;

   b) Central computerized registration and randomization, where appropriate, of all patients on ACE or Consortium protocols, or alternative non-computerized methods when appropriate;

   c) Computerized study forms and systems for the remote entry and transmission of patient data from clinical sites to the central data management facility, or alternative non-computerized methods when appropriate;

   d) Quality assurance and quality control procedures to evaluate and, when necessary, improve the accuracy, timeliness and completeness of data submitted by the clinical sites, including verification of the clinical and laboratory data used to determine that study participants have reached protocol-defined endpoints;

e) The development, implementation and maintenance of security requirements, including:

1) An Automated Information System (AIS) Security Profile, which at a minimum shall include: the System's Security Plan (SSP); the Risk Analysis (RA); the Continuity of Operations Plan (COOP; also known as the Contingency Plan);

2) A log or record of the results from testing the COOP, any existing plans and progress reports for implementing additional security safeguards and controls; and the system access authorization list. The profile shall be kept up-to-date for review and potential inspection upon demand by NIH/DHHS authorized agents. Upon request, copies of specified profile documents shall be presented to NIH/DHHS for its own system's security reporting purposes;

3) The preparation and submission, for Project Officer approval, of an RA following the guidance given in DHHS AISSP Handbook (http://irm.cit.nih.gov/policy/aissp.html). The RA is to be maintained and updated every three years, or in advance of implementing major system modifications or enhancements;

4) The preparation and submission of an annual SSP, following the instruction in OMB Bulletin 90-08, for review and approval by the Project Officer and the NIH SSO (http://irm.cit.nih.gov/itmra/omb90-08.html);

5) The development and maintenance of an up-to-date COOP following the guidance in DHHS AISSP Handbook (http://irm.cit.nih.gov/policy/aissp.html). At a minimum, the COOP shall cover emergency operations, backup operations, and recovery plans to assure continuous operations of the system's facility. COOP testing shall be conducted and the results recorded at least every six months;

6) Plans, procedures, and a recommended schedule and budget for implementation of security safeguards required to satisfy the anticipated conditions of acquiring data from clinical and mechanistic study sites. This includes data integrity and security during electronic transmission, or during transit from the sites to the SACCC if non-electronic data transmission is used. All patient identifiable data is subject to the Privacy Act and DHHS regulations; and

7) Provision for the appropriate labeling, storage, handling, and disposal of sensitive or controlled data, media, and output.

f) Electronic communication linkages among ACE or Consortium clinical and mechanistic study sites, the SACCC, the NIAID, the appropriate Steering or Operations Committee members.

*[SEE NOTE TO OFFEROR: #6]*

6. **Conduct clinical site monitoring and training for all ACE and Consortium clinical sites**. The Contractor shall establish a system to monitor ACE and Consortium clinical sites and to train clinical, technical, data management and administrative site staff, including development and implementation of a set of Standard Operating Procedures (SOP) delineating the policies, procedures and requirements of the ACEs, the Consortium and the FDA. Training shall include protection of human subjects, and specifically protection of children:

See: http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm; see subpart D, sections 46.401-46.409

The monitoring and training system shall adhere to the NIH policy for data and safety monitoring, released on June 10, 1998 (http://www.nih.gov/grants/guide/notice-files/not98-084.html). The clinical site monitoring and training system shall include, but not be limited to:

a) Site establishment visits for all ACE and Consortium clinical sites as new clinical sites are added to the programs. These initial site visits shall encompass: an assessment of the adequacy of all site facilities to be used for clinical trials, e.g., pharmacy, clinical unit, and patient record storage areas; a thorough explanation to site personnel of Federal regulations governing informed consent, Institutional Review Boards, responsibilities of sponsors and investigators, and protection of human subjects from research risks; a thorough explanation of ACE and Consortium policies and procedures and good clinical practices, and, if necessary, providing good clinical practices training to appropriate site personnel; and a confirmation that appropriate site personnel have completed human subjects training;

b) Interim site visits to: (i) assess site compliance with the requirements for ACE and Consortium clinical protocols being conducted, including: adherence to inclusion and exclusion criteria; reporting of serious adverse events; the appropriate collection, storage and transport of patient samples; the accuracy, timeliness and completeness of data collection and entry; clinical records maintenance; and study product accountability; and (ii) assess the various components of the operation and management of the clinical sites, including: site management, organization and utilization of the site staff; communication among clinical, technical and administrative staff; and the adequacy of site facilities and study equipment;

c) Standardized training for clinical site staff for the initiation of all ACE and Consortium protocols via conference calls and meetings, as well as the development of a Manual of Operations for each clinical protocol delineating specific instructions and requirements necessary for the appropriate implementation and monitoring of each clinical trial by site personnel, and the provision of travel expenses associated with group meetings of clinical site personnel, when necessary to ensure appropriate training;

d) Identification of site-specific problems and development of recommendations for the improvement of site performance with respect to: the overall management and coordination of the clinical site; adherence to SACCC Standard Operating Procedures, protocol requirements as specified in Manuals of Operations and Federal regulatory requirements; the quality, timeliness and accuracy of data collection and management, and other relevant improvements. This shall include the preparation of written site visit reports on the findings resulting from clinical site visits, including delineation of specific problems and recommendations for improvements, when necessary, presentation to the NIAID, ACE Steering Committee or Consortium Operations Committee; and

e) A drug accountability audit (annually or as necessary) on a sampling of active protocols at each clinical site.

*[SEE NOTE TO OFFEROR: #7]*

7. **Provide support for regulatory functions and requirements associated with Investigational New Drug (IND) applications** and Investigational Device Exemptions (IDE) applications and the design, conduct, monitoring and analysis of clinical trials of experimental therapies. This shall include:

a) Establishing and maintaining a computerized tracking system for the receipt, follow-up, reporting, and disposition of adverse events for all ACE and Consortium clinical trials to the Food and Drug Administration (FDA), the NIAID, appropriate ACE or Consortium investigators, Independent Medical Monitor, and NIAID DSMB when appropriate. All procedures and systems must meet the guidelines and regulations of the FDA as related to processing of Adverse Event Reporting (AER) and safety information. This shall include:

1) Establishing and maintaining a system for SACCC central receipt of AER information 24 hours/day. This may be accomplished by providing appropriately trained health care professionals during normal working hours and utilizing an answering machine/service after normal working hours and on weekends;

2) Establishing and maintaining a toll-free 800 telephone service for the receipt and triage of telephone calls from study participants concerning potentially serious problems that may require immediate attention by clinical site personnel. This service shall provide pre-recorded instructions and steps to be followed for direct patient reporting of potential problems, including identification of patient name, contact information, present location, protocol, clinical site, treating physician and nurse coordinator, and other relevant information. This service shall also provide for the notification of appropriate clinical site personnel or back-up on call site personnel within two (2) hours of the receipt of a patient telephone call.

3) Providing experienced clinical personnel, with autoimmune disease and transplantation specific medical knowledge, as may be necessary to evaluate adverse event reports received from ACE and Consortium clinical sites, and working with clinical site staff to clarify information, obtain follow-up information, and/or reconcile discrepancies between adverse event data reported versus adverse event data collected on study forms;

4) Within 24 hours of receipt, abstracting and entering adverse event data into the ACE or Consortium central databases;

5) Preparing and distributing, by hard copy or electronic methods, Safety Reports or Information Reports on adverse events following the established FDA, NIAID, ACE or Consortium guidelines and regulations;

6) Developing and distributing to participating clinical sites adverse event reporting forms, standard operating procedures for processing adverse event data, and appropriate instructions or manuals. The forms shall be developed in coordination with ACE and Consortium investigators and shall conform to NIH, NIAID and FDA guidelines and regulations;

7) Developing, implementing and maintaining quality control/assurance procedures and ongoing training to ensure consistency, completeness and accuracy of adverse event reporting, coding and data entry; and

8) Generating and submitting reports to the Project Officer documenting site performance, as measured by accuracy and completeness of Adverse Event Reports, time required for response to queries, and SACCC performance, as measured by timely adverse event report disposition (i.e., time from receipt to entry into central databases, time from receipt to FDA reporting where applicable, and other tracking parameters identified by the Project Officer). These reports shall be prepared and submitted monthly or more frequently as may be necessary, as determined by the Project Officer.

b) Develop and maintain a computerized clinical site registration system including, but not limited to, the following tasks:

1) Filing and tracking registration documentation submitted by clinical sites;

2) Preparing and submitting to the FDA, on a regular basis, the required registration documentation, including copies of the FDA 1572 forms, Curricula Vitae, Institutional Review Board (IRB) approval of each protocol, and IRB-approved consent forms for each protocol;

3) Responding to queries on the status of site registration from the clinical sites, NIAID and the ACE Steering Committee or the Consortium Operations Committee; and

4) Confirming completion of all procedures necessary for study registration, and notifying clinical sites that registration has been completed for a particular protocol so that study products may be ordered and distributed.

c) Prepare, distribute and track Investigational New Drug (IND) applications and Investigational Device Exemptions (IDE) applications sponsored by NIAID and ACE or Consortium investigators, and, when appropriate, pharmaceutical companies. IND or IDE sponsors for ACE or Consortium clinical trials may include the NIAID, individual Consortium investigators, and/or pharmaceutical companies. The Contractor shall be responsible for carrying out all regulatory requirements for NIAID- and investigator-sponsored INDs or IDEs. In instances where the pharmaceutical company serves as the IND or IDE sponsor, the Contractor shall <u>not</u> be responsible for carrying out the regulatory functions outlined above, but the SACCC shall be responsible for the non-regulatory functions associated with these studies, and for cooperating with the IND or IDE sponsor so that regulatory requirements are met (i.e., supplying appropriate data on adverse events reporting).

The responsibilities of the SACCC shall include:

1) Providing technical and administrative assistance in the preparation and assembly of original and subsequent IND and IDE submissions;

2) Gathering information for use in the preparation of IND and IDE submissions, including pre-clinical screening, animal toxicity, chemistry, pharmacology, literature research and clinical research, contacting appropriate Federal and private organizations, including pharmaceutical companies; and editing, indexing, assembling and duplicating acquired data for subsequent submission to the FDA;

3) Obtaining letters from pharmaceutical company sponsors, NIAID and/or individual investigators authorizing the cross-filing of information from other sources for agents studied in clinical protocols under separate INDs or IDEs;

4) Preparing statistical and technical information and other materials for meetings with officials of the FDA regarding the design, implementation and monitoring of ACE or Consortium clinical trials and IND or IDE approval; responding to specific inquiries from FDA officials concerning clinical protocol design and IND or IDE submissions; and, when necessary, making presentations to FDA officials to explain protocol design and supporting safety, toxicity and efficacy data, clarify questions, and address concerns associated with IND or IDE approval;

5) Preparing, distributing and tracking of IND or IDE modifications as required to meet FDA requirements; and

6) Maintaining files on all IND or IDE correspondence and submissions to the FDA for ACE or Consortium sponsored clinical trials.

d) Assist in the preparation of FDA-required IND or IDE sponsor's interim and annual reports. These reports include narrative analysis and tabular summaries of all results of clinical trials. This includes retrieving and summarizing information to be included in FDA annual reports, drawn from, but not limited to: chronologies, pharmaceutical company information, the latest protocol versions, schema/synopsis depicting the protocols, comparison charts of protocol requirements, statistical analyses, relevant abstracts, posters, papers and presentations, copies of adverse event summary reports, and lists of all submissions to the FDA. The Contractor shall provide copies of all interim and annual reports to the FDA, the Project Officer, the individual Consortium investigators as may be necessary.

*[SEE NOTE TO OFFEROR: #8]*

8. **Establish and manage a system for the distribution and quality control of study products and biological samples**. It is anticipated that approximately 50% of clinical trials will have their study products handled through this SACCC-managed system of distribution and quality control, while approximately 50% of clinical trials will have study products shipped directly to clinical site pharmacists. For those products shipped directly to clinical site pharmacists, the SACCC will work with the pharmacists to assure both appropriate distribution of study products and quality control. The responsibilities of the Contractor with respect to the distribution and quality control of study products include:

a) Receipt and storage of study products, including:

1) Receiving shipments of study products from a variety of sources, including domestic contract manufacturers or packagers, commercial pharmaceutical companies, and foreign pharmaceutical companies and suppliers; reconciling shipping lists; noting conditions of receipt; and notifying Project Officer of any discrepancies or problems;

2) Receiving and processing through U.S. Customs any shipments from foreign suppliers;

3) Storing products as indicated on the manufacturer's label;

4) Monitoring storage conditions to guarantee and document continuous proper storage; and

5) Ensuring that all applicable FDA current Good Manufacturing Practice regulations are met.

b) Labeling and packaging of study products, including:

1) Labeling and packaging study products to provide supplies suitable for dispensing to individual patients at clinical sites, using, where applicable, randomization schemes with patient numbers and corresponding treatment assignments;

2) Maintaining accurate records of all such labeled and packaged study products;

3) Providing the capability for patient specific, unit of use packaging, including blister packaging, when required;

4) Providing the capability to affix auxiliary labels for use on certain products and on outer shipping cartons; and

5) Providing facilities for the preparation of patient specific solid and liquid dosage forms

c) Inventory control/quality assurance, including performing a physical inventory of supplies for each protocol at least monthly, notifying the Project Officer of any discrepancies that cannot be reconciled with the current inventory, and monitoring use rate and notifying the Project Officer of low inventories or unusual increases in product requests from clinical sites.

d) Shipping and distribution of study products, including:

1) Processing Investigational Agent Request forms on a daily basis, confirming that the order is from an authorized ACE or Consortium clinical site, filling the order and packaging the appropriate protocol-specific research product, dosage and quantity;

2) Supplying shipping cartons, cushioning materials, necessary labels (e.g., fragile), sealing tape, insulation materials, and all other supplies necessary to ensure safe and intact arrival of study products;

3) Supplying sufficient quantities of appropriate packaging (e.g., wet ice, dry ice, or cold packs) to ensure the safe and intact arrival of products requiring maintenance at low temperatures;

4) Shipping study agents to ACE or Consortium clinical sites so that shipments are received in a timely fashion. On a routine basis, most shipments should arrive within 24 hours.

5) Obtaining the appropriate licenses and permits required by local, state and Federal authorities for the safe import, storage and distribution of drugs, as well as the appropriate interstate, intrastate and foreign import/export shipping licenses and permits for transporting biologics and drugs;

6) On occasion, making shipments after hours or on weekends, as required. Except for emergency shipments or other extraordinary tasks, the Contractor/subcontractor shall be open and accessible during regular business hours; and

7) Providing storage for and performing the packaging and shipping of reports, documents, and other relevant items related to study products distributed. All original Investigational Agent Request forms shall be retained for the duration of the contract and shall be accessible for audit.

e) Pharmaceutical services, including:

1) Reviewing ACE or Consortium clinical protocols and providing the Project Officer with a written protocol evaluation, usually 1-2 pages in length, including estimates of the quantity of study products needed, comments regarding product handling concerns or packaging requirements;

2) Providing product information (e.g., special handling or shipping, study product preparation) to clinical site pharmacists or patients with every shipment;

3) Providing product ordering, transfer or return information to clinical site pharmacists or study participants;

4) Authorizing the transfer of products designated for one protocol to another, as permitted by FDA regulations and/or the pharmaceutical sponsor, and maintaining copies of Investigational Agent Transfer forms for the duration of the contract;

5) Providing evaluations of current study product usage and projections of anticipated requirements to manufacturers on a quarterly basis or as directed by the Project Officer. These evaluations will be reviewed and approved by the Project Officer before forwarding to manufacturers;

6) Preparing protocol-specific documents providing information regarding study product packaging, dosage strength and labeling for distribution to clinical site pharmacists; and

7) Establishing and maintaining a secured web site for clinical site pharmacists including but not limited to: protocol-specific information and requirements related to study products; procedures and forms for ordering study products; procedures and requirements for the return of study products; instructions to be provided to study participants; and other relevant information.

f) Provide security/safety measures and procedures, including: 24-hour security to prevent theft, misuse or damage; an automated 24-hour temperature monitoring system to ensure maintenance of appropriate temperature storage conditions; programs or systems for fire protection; and training on safety, security and appropriate handling of investigational agents to all personnel with access to the drug storage facility. The Contractor shall also be required to meet the requirements of the Drug Enforcement Agency for the storage of controlled substances (http://www.usdoj.gov/dea/agency/csa.htm).

g) Process and dispose of returned drugs, including: identifying and notifying affected investigators in the event that a lot of study product is recalled by the manufacturer or reaches the limit on its useful shelf life; receiving recalled, expired or unused study products returned from clinical sites and processing returns in conformance with local, state and Federal regulations; providing for the quarantine of returned products from other inventory; preparing computerized documentation of returns; and disposing of returned products in a manner prescribed by local, state and Federal regulations.

h) Maintain a dedicated computerized data processing system (i.e., a tracking system) to keep inventories and distribution records. All documentation shall be available for annual audits as required by Federal regulations.

*[SEE NOTE TO OFFEROR: #9]*

9. **Coordinate and provide statistical, technical, administrative and logistical support for the activities of the ACE Steering Committee and the Consortium Operations Committee and Study Teams**, which provide advice and recommendations for the overall scientific direction, management and evaluation of this research program. This shall include:

a) As directed by the Project Officer, developing and revising, as necessary, Conflict of Interest (COI) and disclosure forms for all members of the ACE Steering Committee and Consortium Operations Committee, and investigators; coordinating the distribution and receipt of completed forms; provide all forms to the Project Officer;

b) Membership on the ACE Steering Committee and the Consortium Operations Committee by the SACCC Principal Investigator, including participation in all meetings and conference calls convened by these governing bodies;

c) Scheduling, arranging lodging and meeting room facilities, and arranging appropriate teleconferencing services for: (i) two 2-day meetings of the ACEs Steering Committee per year for a six (6) year period, (ii) two 2-day meetings of the Consortium Operations Committee for a five (5) year period, and (iii) an average of bi-monthly conference calls for the Consortium Study Teams for a five (5) year period. The Contractor shall provide for the transportation, meals and lodging expenses associated with participation in these meetings by the non-Federal members of the ACE Steering Committee and the Consortium Operations Committee;

*[SEE NOTE TO OFFEROR: #10]*

d) Scheduling, arranging lodging and meeting room facilities, and arranging appropriate services for all meetings and conference calls of ACE or Consortium Study Teams. The SACCC Principal Investigator, or designated representative, shall participate in all clinical study team meetings and conference calls;

*[SEE NOTE TO OFFEROR: #11]*

e) Preparing, assisting in the preparation of, and distributing in advance of ACE Steering Committee and Consortium Operations Committee and clinical trials meetings and conference calls a variety of materials, reports, analyses and recommendations for review. This shall include, but not be limited to:

1) Proposed concepts for clinical trials and mechanistic studies;

2) Proposed detailed protocols for approved clinical trials and detailed research designs for approved mechanistic studies;

3) Proposals for modifications in the design of approved clinical trials and mechanistic studies;

4) Status of and issues surrounding FDA approval of INDs;

5) Status reports on the implementation of approved clinical trials and mechanistic studies, including accrual, retention, loss to follow-up, problems and issues with respect to data management and quality assurance, and recommendations for modifications/improvements where necessary;

6) Interim and final analyses of the results of clinical trials and mechanistic and biomarker studies, including recommendations for protocol and mechanistic and biomarker study modifications to ensure the validity, reliability and feasibility of completing approved studies; and

7) Brief summaries of all decisions and recommendations of the ACE Steering Committee and the Consortium Operations Committee and the clinical trial study Teams.

f) Assisting the NIAID and the ACE Steering Committee and Consortium Operations Committee in the preparation of Standard Operations Procedures for governance of the programs. This shall include, but not be limited to, policies and procedures governing:

1) The development, review, modification, and approval/disapproval of proposed concepts and detailed protocols for clinical trials and detailed research designs for mechanistic studies, including the development of criteria for the evaluation;

2) The monitoring of progress with respect to the implementation of approved clinical trials and mechanistic studies, including appropriate reporting requirements for ongoing progress reviews and criteria for expanding, curtailing or discontinuing approved studies;

3) The development and implementation of criteria and procedures for the evaluation of clinical and mechanistic study site performance, as well as policies for correcting site deficiencies and/or curtailing or eliminating approved sites;

4) Requests for interim and final analyses of clinical and laboratory study results;

5) The addition of clinical and mechanistic study sites to accommodate new knowledge and scientific opportunities; and

6) The preparation and review of scientific reports, manuscripts, abstracts and presentations on ACE and Consortium study results;

10. **Coordinate and provide statistical, technical and administrative support for the activities of the independent Data and Safety Monitoring Boards (DSMB)**, to be appointed by the NIAID to monitor the safety of ACE and Consortium clinical trials. The NIAID DSMB shall be composed of scientific and clinical experts, bioethicists, and other representatives as may be necessary. This shall include:

a) As directed by the Project Officer, developing and revising, as necessary, Conflict of Interest (COI) and disclosure forms for all permanent and ad hoc DSMB members; coordinating the distribution and receipt of completed forms; providing all forms to the Project Officer; and

b) Scheduling, arranging lodging and meeting room facilities, and arranging teleconference services for meetings and conference calls of the NIAID DSMB.

*[SEE NOTE TO OFFEROR: #12]*

c) Distributing copies of all protocols for clinical trials and mechanistic studies to the NIAID DSMB members and NIAID for review, including forms and procedures for obtaining informed consent; facilitate communication among members of DSMB; and provide summaries of all comments received from NIAID DSMB members to the NIAID Project Officer.

d) Preparing a variety of interim and final statistical analyses and reports for review by the NIAID DSMB, including:

1) Analyses of ongoing pilot and efficacy trials with respect to safety, toxicity and efficacy, including adverse event reports and assessments;

2) Study accrual and retention data, including issues and problems associated with the recruitment and retention of study participants; and

3) Recommendations for improvements and modifications in study protocols as may be necessary to enhance recruitment and retention, ensure the feasibility and scientific validity of inclusion and exclusion criteria and comparison and control groups, and assess the techniques and methodologies used to delineate underlying mechanisms, and to study biomarkers.

e) Preparing summaries of the results of all NIAID DSMB meetings for review and approval by the Project Officer. This includes: preparation of confidential comments and summary; summary of recommendations to investigators, ACE Steering Committee or Consortium Operations Committee. The SACCC may participate in preparing responses to DSMB comments and designing modifications to ACE and Consortium approved studies as necessary.

11. **Ensure an orderly and timely transfer of all data, information, and documentation from the incumbent contractor/subcontractor necessary to proceed with the functions of the SACCC as detailed above.**

12. **Prior to completion, ensure an orderly transition of contract-related materials to a successor contractor or the Government. Six months prior to the completion date of this contract, a transition plan shall be submitted to the Project Officer for approval.**

**[END OF STATEMENT OF WORK]**

**Notes To Offerors**

**Statistical & Clinical Coordinating Center for Autoimmune Diseases Clinical Trials (SACCC- ADCT)**
**DAIT-02-23**

**General Notes to Offerors:**

- The work proposed under this solicitation is being performed during FY2001 by EMMES Corporation and subcontractors.

- The Autoimmunity Centers of Excellence are supported through a cooperative agreement from the NIAID. The present Centers, which are listed in APPENDIX A, will remain in place through FY2002. The NIAID intends to recompete and renew this program in FY2003 for a period of five years; thus the specific Centers may change in FY2003. The Autoimmune Diseases Transplantation Consortium, supported through contracts to Duke University, Medical College of Wisconsin, and Northwestern University, includes persons listed in APPENDIX B. This Consortium will perform clinical trials over the next five years. The Statistical and Clinical Coordinating Center, which is solicited in this RFP, shall provide support for the ACEs and the Consortium for a total period of seven (7) years.

- A broad range of statistical, technical, regulatory, clinical trial coordination and monitoring, and administrative expertise will be necessary to carry out the requirements of this solicitation. The Government recognizes that a single institution or organization may not have the expertise and facilities necessary to perform all requirements and, therefore, that it may be necessary for the Prime Contractor to subcontract portions of the work to be performed. Offerors shall have flexibility in proposing a structure and organization capable of meeting the requirements of this work statement. However, the Prime Contractor shall be required to demonstrate proven expertise in providing statistical leadership for the design of clinical trials and the analysis of study results.

- Because the design and development path for the research to be carried out by the ACEs and the Autoimmune Diseases Transplantation Consortium can not be entirely anticipated, the Contractor shall be required to propose a plan for accommodating changes in the scientific direction of the clinical research to be conducted in order to capitalize on new scientific findings and therapeutic approaches relative to the functions of the Statistical and Clinical Coordinating Center. This plan shall include proposed methods to redirect personnel and fiscal resources, provide for the incorporation of additional statistical, clinical, technical, and administrative expertise, and curtail or discontinue personnel and fiscal resources when necessary to accommodate changing scientific priorities and opportunities.

- Experimental agents to be evaluated by the Consortium will be provided at no cost to the Contractor. Therefore, Business Proposals shall not include any costs associated with the purchase of investigational agents.

**NOTES TO OFFEROR**

**Note 1**

Technical Proposals shall include documentation of the qualifications, knowledge, relevant experience, education, competence and availability of all proposed personnel of the Prime Contractor and proposed subcontractors, including the Principal Investigator and the personnel proposed to carry out the functions specified in item 1. a) through i) of the Statement of Work. Documentation shall also include all previous and current projects of a similar nature, including the grant or contract number, the sponsoring agency, the project officer, and description of the project. Curricula Vitae of all proposed personnel shall be included in the Technical Proposal. In addition, the Offeror shall describe the responsibilities and level of effort of all proposed personnel who will be assigned to the contract, including subcontractors, as well as an administrative framework indicating clear lines of authority and a detailed work plan for achieving contract objectives. Proposals for multi-institutional or multi-organizational arrangements shall specifically address how inter-institutional coordination and communication will be carried out, potential inter-institutional problems or obstacles that could be anticipated, and methods/procedures proposed to overcome any such problems or obstacles. All costs associated with proposed personnel shall be provided in the Business Proposal.

**Note 2**

Technical Proposals shall include a discussion of the statistical and clinical trial design features and considerations of importance in: 1) developing, implementing and monitoring clinical trials designed to prevent or treat autoimmune diseases with immunomodulatory or tolerogenic approaches, including study design considerations associated with the partial or total withdrawal of standard therapy, the provision of adequate rescue therapies, and potential for malignancy and infectious complications of these approaches; and 2) developing, implementing and monitoring clinical trials of immune ablation and stem cell rescue for the treatment of autoimmune diseases, including study design considerations associated with risk:benefit analysis, evaluation of short term and durable responses, inclusion of comparison or control groups, and recruitment of subjects.

**Note 3**

For cost estimating purposes, Offerors shall assume that: (1) in the first year of this contract, 2 single site ACE studies, involving 15 subjects each; 2 multi-site ACE clinical trials, involving an average of 3 sites, and 6 patients per site; and one Consortium clinical trial with 8 sites and 4 patients per site will be ongoing; (2) in years 2-6 of this contract, up to 6 clinical trials will be ongoing per year, resulting in a total of approximately sixteen clinical sites, and will involve a total of approximately 150 study participants per year.

**Note 4**

Technical Proposals shall include a discussion of the statistical and clinical trial design features and considerations of importance in developing, implementing, and monitoring studies of the underlying mechanisms of 1) immunomodulatory or tolerogenic agents in the treatment or prevention of autoimmune diseases and 2) immune ablation and stem cell rescue in treatment of autoimmune diseases. This shall include statistical aspects associated with the ability to define differences among patient populations, define disease stage and activity, and assess disease progression.

**Note 5**

For cost estimating purposes, Offerors shall assume that: (1) in the first year of this contract, two mechanistic studies will be ongoing; and (2) in years 2-6 of this contract, approximately three mechanistic studies will utilize this contract/per year.

**Note 6**

Technical Proposals shall include a detailed plan for establishing and administering the data collection, management retrieval, quality assurance and security tasks specified above, including the specific computerized and non-computerized systems proposed, the capabilities of these systems, and the rationale for and feasibility of the proposed systems in terms of meeting the requirements set forth in the work statement. Technical Proposals shall also include a proposed plan for ensuring the accuracy, timeliness and completeness of study data, including the frequency and extent of data verification, procedures for reporting problems with the quality, timeliness and accuracy of data, proposed methods to improve site performance, and security procedures.

**Note 7**

Technical Proposals shall include a proposed plan for clinical site monitoring and training, addressing the requirements set forth in this item. In addition, Technical Proposals shall include samples of similar plans, policies and procedures currently or previously used by the Offeror to implement clinical site monitoring and training activities. For cost estimating purposes, Offerors shall assume that: (i) two one-day site initiation visits will be conducted for 2 ACE sites and four two day site visits will be conducted on one Consortium trial in FY 2002; (ii) in the second and subsequent years of the contract, an average of four two-day site initiation visits will be conducted per year; (iii) interim site visits for all Consortium sites will be conducted at least annually, or more frequently as may be necessary.

**Note 8**

IND sponsors for Consortium clinical trials may include the NIAID, individual ACE or Consortium investigators, and/or pharmaceutical companies. The Contractor shall be responsible for carrying out all regulatory requirements for NIAID- and investigator-sponsored INDs and IDEs. In instances where the pharmaceutical company serves as the IND or IDE sponsor, the Contractor shall not be responsible for carrying out the regulatory functions outlined above, but the SACCC shall be responsible for the non-regulatory functions associated with these studies, and for cooperating with the IND sponsor so that regulatory requirements are met (i.e., supplying appropriate data on adverse events reporting). For cost estimating purposes, Offerors shall assume that approximately 70 percent of the clinical trials conducted by the Consortium will involve IND sponsorship by the NIAID or by individual ACE or Consortium investigators. **THIS CONTRACT WILL NOT SUPPORT THE PURCHASE OF GENERAL PURPOSE ADP EQUIPMENT FOR THE REQUIREMENTS SPECIFIED IN ITEM 7 OF THE WORK STATEMENT. THEREFORE, OFFERORS SHALL NOT INCLUDE ANY COSTS ASSOCIATED WITH THE PURCHASE OF SUCH EQUIPMENT IN THEIR BUSINESS PROPOSALS.**

**Note 9**

Technical Proposals shall include: (i) a plan for the technical approach and methods proposed to carry out the requirements set forth in item 8 with respect to establishing and managing a system for the receipt, packaging, distribution, quality assurance, security, and inventory functions associated with study products for clinical trials; (ii) the documented qualifications, knowledge and relevant experience of proposed personnel; (iii) a detailed plan for the proposed facility and a list of all equipment and resources to be dedicated to the contract; (iv) adherence to FDA Good Manufacturing Practice requirements, including copies of any FDA audits conducted during the past four (4) years; and (v) a copy of DEA license as documentation of compliance with DEA requirements.

**Note 10**

For cost estimating purposes, Offerors shall assume the following: (i) the ACE Steering Committee will be composed of approximately eight (8) non-Federal members, including 2 from the west coast, 2 from the midwest and 4 from the east coast; (ii) 50% of the meetings of the ACE Steering Committee will be held in the Bethesda, Maryland area, and 50% of these meetings will be held in the Chicago, Illinois area; (iii) the Consortium Operations Committee will be composed of ten (10) non-Federal members, including 5 from the west cost, 3 from the midwest, and 2 from the east coast, (iv) 50% of the meetings of the Consortium Operations Committee will be held in the Bethesda, Maryland area, and 50% of these meetings will be held in the Chicago, Illinois area; (v) an average of 2 non-Committee members per meeting will attend both the ACE and the Consortium meetings; and (iv) the SACCC Principal Investigator and 2 additional SACCC staff will attend these meetings.

**Note 11**

For cost estimating purposes, Offerors shall assume the following: (i) the ACE and Consortium will establish five (5) Study Teams; (ii) the Study Teams, composed of approximately five (5) members each, will meet for at least 1 two-day meeting annually (together with one of the Steering or Operations Committee meetings) for a five year period, and will conduct monthly conference calls in year 1 and at least bi-monthly calls in years 2-6; and (iii ) 50% of the Subcommittee meetings will be held in the Bethesda, Maryland area, and 50% of these meetings will be held in the Chicago, Illinois area.

**Note 12**

For cost estimating purposes, Offerors shall assume the following: (i) two DSMBs, composed of approximately seven individuals (6 full-time members, and an average of 1 ad hoc member per meeting) each will be appointed by the NIAID to oversee the clinical trials of the ACEs and the Consortium; (ii) each DSMB will meet semi-annually (one day and one night) in all years in the Bethesda, Maryland area; (iii) quarterly conference calls of the DSMB will be conducted; and (iv) transportation, meals and lodging costs associated with the participation of non-Federal DSMB members shall be provided for by the SACCC.

**APPENDIX A**

# AUTOIMMUNITY CENTERS OF EXCELLENCE STEERING COMMITTEE

| INVESTIGATORS | INVESTIGATORS |
|---|---|
| Brian L. Kotzin, MD<br>Professor of Medicine and Immunology<br>Co-Head, Division of Clinical Immunology (B-164)<br>University of Colorado Health Sciences Center<br>4200 East Ninth Avenue<br>Denver, CO 80262<br>Tel: 303-315-6977<br>Fax: 303-315-7642<br>E-mail: brian.kotzin@uchsc.edu | Samia J. Khoury, MD<br>Associate Professor of Neurology<br>Director, Clinical Immunology Laboratory<br>Center for Neurologic Diseases<br>Brigham and Women's Hospital<br>77 Avenue Louis Pasteur<br>Boston, MA 02115<br>Tel: 617-525-5370<br>Fax: 617-525-5252<br>E-mail: skhoury@rics.bwh.harvard.edu |
| Leonard Chess, MD<br>Professor of Medicine<br>Director of Rheumatology<br>Columbia University College of P&S<br>630 West 168th Street<br>PH 8E, Suite 101<br>New York, NY 10032<br>Tel: 212-305-9984<br>Fax: 212-305-4943<br>E-mail: LC19@columbia.edu | Robert Winchester, MD<br>Division of Autoimmune and Molecular Diseases<br>Columbia University<br>College of Physicians & Surgeons<br>PH4-477<br>630W 168th Street<br>New York City, NY 10032<br>Tel: 212-305-7226<br>Fax: 212-305-9078<br>E-mail: RJW8@columbia.edu |
| George S. Eisenbarth, MD<br>Barbara Davis Center for Childhood Diabetes<br>4200 E. 9th Ave, Box B140<br>Denver, CO 80401<br>Tel: 303-315-4891<br>Fax: 303-315-4892<br>E-mail: george.eisenbarth@uchsc.edu | A.M. Rostami, MD, PhD<br>Department of Neurology<br>University of Pennsylvania Medical Center<br>3400 Spruce Street<br>Philadelphia, PA 19104<br>Tel: 215-662-6557<br>Fax: 215-573-2107<br>E-mail: rostamia@mail.med.upenn.edu |
| Robert A. Eisenberg, MD<br>Chief, Division of Rheumatology<br>University of Pennsylvania<br>502 Maloney Building<br>3400 Spruce Street<br>Philadelphia, PA 19104-4283<br>Tel: 215-662-4864<br>Fax: 215-662-4500<br>E-mail: raemd@mail.med.upenn.edu | David A. Hafler, MD<br>Breakstone Professor of Neurology<br>(Neuroscience)<br>Harvard Medical School<br>77 Ave Louis Pasteur, HIM Room 786<br>Boston, MA 02115<br>Tel: 617-525-5330<br>Fax: 617-525-5333<br>E-mail: dhafler@rics.bwh.harvard.edu |

**APPENDIX B**

## STEM CELL TRANSPLANTATION FOR TREATMENT OF AUTOIMMUNE DISEASES CONSORTIUM

| INVESTIGATORS | INVESTIGATORS |
|---|---|
| Christopher Bredeson, MD<br>Assistant Scientific Director<br>Medical College of Wisconsin<br>Statistical Center, IBMTR/ABMTR<br>8701 Watertown Plank Rd.<br>Milwaukee, Wisconsin 53226<br>Telephone: (414) 456-8787<br>Fax: (414) 456-6530<br>Email: bredeson@mcw.edu | Ken Kalunian, M.D.<br>Associate Professor of Medicine<br>UCLA School of Medicine<br>200 UCLA Medical Plaza #365<br>Los Angeles, CA 90095<br>Telephone: (310) 825-5078<br>Fax: (310) 794-9718<br>Email: kkalunian@mednet.ucla.edu |
| Richard Burt, M.D.<br>Associate Professor<br>Northwestern Memorial Hospital<br>250 E. Superior Street Room 162<br>Chicago, IL 60611<br>Telephone: (312) 695-2010<br>Fax: (312) 908-8885<br>Email: rburt@northwestern.edu | Arthur Kavanaugh, M.D.<br>Associate Professor-UCSD<br>Division of Rheumatology, Allergy and Immunology<br>9310 Campus Point Drive Suite A111<br>La Jolla, CA 92037-0943<br>Telephone: (858) 657-7044<br>Fax : (858) 657-7045<br>Email: akavanaugh@ucsd.edu |
| Daniel Furst, M.D.<br>Virginia Mason Medical Center<br>1000 Seneca St.<br>Mail Stop R1-RC<br>Seattle, WA 98101<br>Telephone: (206) 223-6836 ext 0<br>Fax: (206) 223-7554<br>Email: crgdef@vmmc.org | Lorri Lobeck, M.D.<br>Assistant Professor of Neurology<br>Froedtert Hospital<br>Department of Neurology<br>9200 W. Wisconsin Avenue<br>Milwaukee, WI 53226<br>Telephone: (414) 454-5219<br>Fax: (414) 259-0469<br>Email: llobeck@mcw.edu |
| Bevra H. Hahn, M.D.<br>Professor of Medicine<br>Chief, Division of Rheumatology<br>Department of Medicine<br>University of California, Los Angeles<br>1000 Veteran Avenue, Room 32-59, Box 951607<br>Los Angeles, CA 90095-1670<br>Telephone: (310) 825-7991<br>Fax: (310) 206-9797<br>Email: bhahn@mednet.ucla.edu | Peter McSweeney, M.D.<br>Associate Professor of Medicine<br>Bone Marrow Transplant Program<br>University of Colorado<br>4200 East Ninth Avenue, Box B190<br>Denver, Colorado 80262<br>Telephone: (303) 372 9267<br>Fax: (303) 372 9003<br>Email: Peter.McSweeney@UCHSC.edu |
| Richard A. Nash, M.D.<br>Associate Member<br>Fred Hutchinson Cancer Research Center<br>University of Washington<br>1100 Fairview Ave North<br>Mail stop D1-100<br>Seattle, WA 98109-1024<br>Telephone: (206) 667-4978<br>Fax: (206) 667-6124<br>Email: rnash@fhcrc.org | Ann Traynor, M.D.<br>Associate Professor<br>Northwestern Memorial Hospital<br>250 E. Superior Street<br>Room 162<br>Chicago, IL 60611<br>Téléphone: (312) 695-1664 (pager#)<br>Fax : (312) 908-8885<br>Email : a-traynor@nwu.edu |

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|---|---|
| Carol Wallace, M.D.<br>Children's Hospital and Medical Center<br>4800 Sandpoint Way NE<br>P.O. Box 5371<br>Seattle, WA 98105<br>Telephone: (206) 526-2057<br>Fax: (206) 527-3852<br>Email: cwallace@u.washington.edu | Jerry S. Wolinsky, M.D.<br>Professor of Neurology<br>Director, Multiple Sclerosis<br>Research Group<br>University of Texas<br>Health Science Center<br>6431 Fannin Street<br>Houston, TX 77030<br>Telephone: (713) 500-7048<br>Fax: (713) 500-7041<br>Email: jswolinsky@aol.com |
| Harry Openshaw, M.D.<br>City of Hope National Medical Center<br>1500 East Duarte Road<br>Duarte, CA 91010<br>Telephone: (626) 359-8111 ext. 2859<br>Fax: (626) 301-8986 (FAX)<br>Email: hopenshaw@coh.org | Keith M. Sullivan, M.D.<br>James B. Wyngaarden Professor of Medicine<br>Duke University Medical Center<br>Box 3476, DUMC<br>Durham, N.C. 27710<br>Telephone: (919) 681-9507<br>Fax: (919) 681-9599<br>Email: sulli025@mc.duke.edu |
| Richard Pope, M.D.<br>Professor<br>Department of Rheumatology-NU<br>303 E. Chicago Avenue, #3-315<br>Chicago, IL 60611-W121<br>Telephone: (312) 503-8197<br>Fax: (312) 503-0994<br>Email: rmp158@northwestern.edu | David Pisetsky, M.D.<br>Professor of Medicine<br>Division of Rheumatology<br>Box 151G VA Medical Center<br>Durham, N.C. 27705<br>Telephone: (919) 286-6835<br>Fax: (919) 286-6891<br>Email: piset001@mc.duke.edu |

**Reporting Requirements**
**Statistical & Clinical Coordinating Center for Autoimmune Diseases Clinical Trials (SACCC- ADCT)**
**RFP DAIT-02-23**

The Contractor shall submit to the Contracting Officer and to the Project Officer technical progress reports covering the work accomplished during each reporting period. These reports shall be brief and factual and prepared in accordance with the format specified below.

A. MONTHLY ACCRUAL AND SITE REGISTRATION REPORT

Every month, the Contractor shall submit a report for each open clinical protocol sponsored by the ACEs and the Consortium, summarizing:

1. For each clinical site enrolling study participants in open clinical protocols: projected overall accrual at each site; date of first enrollment; actual accrual to date; summary of all eligible patients per month and to date; and reasons for non-entry of eligible patients;

2. For each clinical site in the process of registering and obtaining approval to participate in open clinical protocols: outstanding requirements for approval; anticipated date of approval; projected accrual; and any anticipated problems with protocol approval/implementation;

3. Summary of the projected versus actual accrual to date for all approved clinical sites, and reasons for non-entry of eligible patients;

4. For each approved mechanistic study associated with an open clinical protocol: status of implementation; status of collection, shipping and receipt of patient samples; problems and/or issues associated with the collection, shipping or receipt of patient samples; and recommendations for resolving any such issues or problems; and

5. Recommendations for modifications in study design, clinical site monitoring, or clinical site training appropriate to improve overall or site-specific accrual, including recommendations for increasing the number of participating clinical sites.

**One (1) copy to the NIAID Project Officer.**
**One (1) copy to the ACEs Steering Committee Chair.**
**One (1) copy to the Consortium Operations Committee Chair.**

B. MONTHLY ADVERSE EVENT REPORT

The Contractor shall submit a report on all adverse events for each ACE and Consortium sponsored open clinical protocol, including copies of adverse event report forms.

**One (1) copy to the NIAID Project Officer.**
**One (1) copy to the ACEs Steering Committee Chair**
**One (1) copy to the Consortium Operations Committee Chair.**

C. QUARTERLY STATUS, STATISTICAL AND WORK REPORT ON CONCEPT, PROTOCOL, AND MECHANISTIC STUDY DEVELOPMENT

Every three months, the Contractor shall submit a report summarizing the status of the following for the ACE and Consortium activities, separately and in composite:

1. Proposed Concepts and Protocols for clinical trials, mechanistic studies, including: lead investigator(s); stage of development; step within the NIAID and the ACE and Consortium review process; actions required for final approval, modification or disapproval, including unresolved issues, questions or problems; and timeframe for completion of review, approval, modification or disapproval;

2. Approved concepts for clinical trials and mechanistic studies under development, including: lead investigator(s); stage of development; step within the NIAID and ACEs and Consortium development process; actions required for final approval, modification or disapproval, including unresolved issues, questions or problems; and timeframe for completion of NIAID and Consortium development, approval or disapproval;

3. Clinical protocols and mechanistic studies open to enrollment, including: lead investigator(s); stage of patient enrollment; actions required to meet enrollment projections, including any protocol modification(s) and unresolved issues, questions or problems; and timeframe for completion

4. Copies of all pending and approved concepts;

5. Proposed or ongoing interim and final analyses of the results of clinical trials and mechanistic studies sponsored by the ACEs and Consortium. This shall include:

   a) Title, author(s), brief description and status of approved analyses, including any pending issues, problems or modifications; and

   b) Recommendations for additional interim and final analyses for clinical trials and mechanistic studies;

6. A summary of issues or problems encountered with respect to the NIAID and/or the ACEs or Consortium review and decision-making process, including recommendations for modifications and improvements to enhance the timeliness, efficiency or thoroughness of the review processes; and

7. Any other information the SACCC determines that the NIAID Project Officer should be advised about.

**One (1) Original to the NIAID Contracting Officer.**
**One (1) copy to the NIAID Project Officer.**

D. ANNUAL REPORT

On an annual basis, the Contractor shall submit a report summarizing the results of the entire contract work for the period covered, with separate reports prepared for the requirements of this contract with respect to the activities of the ACEs and the Consortium as specified below. These Annual Reports shall be in sufficient detail to explain comprehensively the results achieved. Annual Reports shall be submitted thirty (30) days prior the anniversary date.

**One (1) Original to the NIAID Contracting Officer.**
**One (1) copy to the Project Officer.**

The Annual Report shall address each of these issues:

1. STATISTICAL DESIGN CONSIDERATIONS

   a) The advantages and disadvantages of the various approaches to the statistical design of ongoing and completed ACEs and Consortium clinical trials and mechanistic studies relevant for the assessment of the safety and efficacy of tested approaches or agents including: control and comparison groups, inclusion and exclusion criteria, sample size; research questions addressed; clinical end-points and immune/surrogate markers measured, number and type of patient samples, and other relevant issues in statistical design; and

   b) Recommendations for improved statistical approaches and methods to enhance the ability to assess disease stage and activity, therapeutic effect and underlying mechanisms.

2. STANDARD OPERATING PROCEDURES, including:

   a) Development and review proposed concepts for clinical trials and mechanistic studies, including criteria for evaluation and prioritization;

   b) Development, review and implementation of approved protocols and mechanistic studies, including criteria for evaluation and prioritization;

c) Monitoring and training at clinical sites with respect to adherence to protocol requirements, data collection and quality assurance, adherence to regulatory requirements, and other relevant monitoring and training;

d) Preparation, review and approval of requests for statistical analyses;

e) Review and approval of publications, abstracts, reports and presentations;

f) Monitoring and evaluating the performance of clinical and mechanistic study sites and procedures for addressing performance problems; and

g) Developing other policies and procedures in conjunction with the NIAID and ACE Steering Committee and the Consortium Operations Committee.

3. CLINICAL SITE MONITORING AND TRAINING, including:

a) Clinical site training activities conducted, including written materials on ACE and Consortium-specific standard operating procedures and protocol-specific requirements;

b) Issues and problems encountered in the training and monitoring of ACE and Consortium clinical sites;

c) Recommendations for modifications/improvements in training materials and/or standard operating procedures to ensure adherence to protocol requirements, standard operating procedures and regulatory requirements.

d) All reports from clinical site establishment and interim site visits, including documentation of site capabilities and deficiencies and remedies implemented to assure the sites are in compliance with all appropriate Federal regulations and ACE and Consortium procedures.

4. THE DISTRIBUTION AND QUALITY CONTROL OF STUDY PRODUCTS, including:
receipt, labeling, storage, distribution, security, inventory quality assurance, shipping, evaluations of usage, and disposition of returned investigational agents.

5. REGULATORY FUNCTIONS AND REQUIREMENTS, including:
the status of INDs and IDEs, issues and problems in the development, FDA review and approval of INDs and IDEs, and recommendations for improvements/modifications in ACE and Consortium regulatory procedures.

6. NIAID DSMB RESPONSIBILITIES AND PROCEDURES, including:
procedures for the review of interim and final analyses of study data and recommendations for improvements in the analyses prepared for DSMB review and the nature and type of study data generated by ACE and Consortium sites.

7. MONITORING PROGRESS AND EVALUATING PERFORMANCE, including:
an assessment of policies and procedures used by the ACEs and Consortium, and recommendations for improvements.

8. ANNUAL AUTOMATED INFORMATION SYSTEM SECURITY REPORT, including:
the Automated Information System (AIS) Security Profile, which at a minimum shall include: the System's Security Plan (SSP); the Risk Analysis (RA); the Continuity of Operations Plan (COOP; also known as the Contingency Plan)

E. FINAL DELIVERABLES:

At the completion of the contract, the Contractor shall deliver to the Project Officer:

1. a cleaned and edited public use data set, on media to be determined at the time of delivery, as specified by the Project Officer,

2. copies of all data management tools, including, but not limited to, data documentation and data dictionaries, data entry software and editing programs to allow reading and analysis of the data;

3. appropriate computer programs capable of: (1) reading and manipulating all data, and (2) creating SAS compatible databases;

4. an audit trail of all raw data corrections, hard copies of the original data collected from study participants from all studies supported by this contract; and

5. all logs and other records related to data collection, entry, editing, analysis and transfer.

F. FINAL TECHNICAL REPORT

In addition, the SACCC will provide a FINAL TECHNICAL REPORT summarizing all SACCC activities for the life of the contract and all final study results and interim results from unfinished clinical trials or mechanistic studies. All study results will include the Principal Investigator; all study sites and participating investigators; enrollment statistics by clinical site (including demographic information on all enrollees) and results of the studies in textual, tabular and graphical format. In addition, the SACCC will provide a 200 word "SUMMARY OF SALIENT RESULTS" detailing the important accomplishments from the ACE and Consortium studies during the performance of the contract.

**One (1) Original to the NIAID Contracting Officer.**
**One (1) copy to the Project Officer.**

G. TECHNICAL REPORT DISTRIBUTION:

| Item # | Type of Deliverable | Description | Initial Report Due | Subsequent Reports Due |
|---|---|---|---|---|
| A. | **MONTHLY ACCRUAL AND SITE REGISTRATION REPORT** | Outlined above. | TBD | Monthly |
| B. | **MONTHLY ADVERSE EVENT REPORT** | Outlined above. | TBD | Monthly |
| C. | **QUARTERLY STATUS, STATISTICAL AND SACCC WORK REPORT** | Outlined above. | TBD | Quarterly |
| D. | **ANNUAL REPORT** | Outlined above. | TBD | Annually |
| E. | **FINAL DELIVERABLES** | Outlined above. | On or before the completion date of the contract. | |
| F. | **FINAL REPORT (WITH SUMMARY OF SALIENT RESULTS)** | Outlined above. | On or before the completion date of the contract. | |

**Addressees**:

| Item(s) # | No. of Copies | Addressee(s) |
|---|---|---|
| A. thru E. | 1 Copy | Project Officer<br>Rockville, MD 20892-___. |
| C. D. and F. | Original | Contracting Officer<br>CMB, DEA, NIAID<br>6700-B Rockledge, Room 2230, MSC 7612<br>Bethesda, MD 20892-7612 |

# PART I - THE SCHEDULE

## SECTIONS B - H -- UNIFORM CONTRACT FORMAT - GENERAL

**A Sample Uniform Contract Format may be found at the following website:**

http://www4.od.nih.gov/ocm/contracts/rfps/sampkt.htm

**[Disregard SECTION I and J of this sample. Those SECTIONS have been incorporated as part of this RFP.]**

# PART II – CONTRACT CLAUSES

**SECTION I - CONTRACT CLAUSES**

**THE FOLLOWING PAGES CONTAIN A LISTING(S) OF GENERAL CLAUSES WHICH WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSES LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP.**

**BECAUSE THIS IS A STREAMLINED RFP, ARTICLES I.2. AND I.3., WHICH IDENTIFY ANY AUTHORIZED ADDITIONS, SUBSTITUTIONS AND/OR MODIFICATIONS TO THE GENERAL CLAUSES, WILL BE BASED ON THE TYPE OF CONTRACT/CONTRACTOR AND WILL BE DETERMINED DURING NEGOTIATIONS.**

**ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT – FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)**

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this URL: http://www.arnet.gov/far/.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CHAPTER 1) CLAUSES

| FAR Clause No. | Date | Title |
|---|---|---|
| 52.202-1 | Dec 2001 | Definitions |
| 52.203-3 | Apr 1984 | Gratuities (Over $100,000) |
| 52.203-5 | Apr 1984 | Covenant Against Contingent Fees (Over $100,000) |
| 52.203-6 | Jul 1995 | Covenant Against Contingent Fees (Over $100,000) |
| 52.203-7 | Jul 1995 | Anti-Kickback Procedures (Over $100,000) |
| 52.203-8 | Jan 1997 | Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000) |
| 52.203-10 | Jan 1997 | Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000) |
| 52.203-12 | Jun 1997 | Limitation on Payments to Influence Certain Federal Transactions (Over $100,000) |
| 52.204-4 | Aug 2000 | Printing/Copying Double-Sided on Recycled Paper (Over $100,000) |
| 52.209-6 | Jul 1995 | Protecting the Governments Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $25,000) |
| 52.215-2 | Jun 1999 | Audit and Records - Negotiation (Over $100,000) |
| 52.215-8 | Oct 1997 | Order of Precedence – Uniform Contract Format |
| 52.215-10 | Oct 1997 | Price Reduction for Defective Cost or Pricing Data |
| 52.215-12 | Oct 1997 | Subcontractor Cost or Pricing Data (Over $500,000) |
| 52.215-14 | Oct 1997 | Integrity of Unit Prices (Over $100,000) |
| 52.215-15 | Dec 1998 | Pension Adjustments and Asset Reversions |
| 52.215-18 | Oct 1997 | Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) Other Than Pensions |
| 52.215-19 | Oct 1997 | Notification of Ownership Changes |
| 52.215-21 | Oct 1997 | Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications |
| 52.216-7 | Mar 2000 | Allowable Cost and Payment |
| 52.216-8 | Mar 1997 | Fixed Fee |
| 52.219-8 | Oct 2000 | Utilization of Small Business Concerns (Over $100,000) |

| | | |
|---|---|---|
| 52.219-9 | Oct 2001 | Small Business Subcontracting Plan (Over $500,000) |
| 52.219-16 | Jan 1999 | Liquidated Damages - Subcontracting Plan (Over $500,000) |
| 52.222-2 | Jul 1990 | Payment for Overtime Premium (Over $100,000) (NOTE: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.) |
| 52.222-3 | Aug 1996 | Convict Labor |
| 52.222-26 | Feb 1999 | Equal Opportunity |
| 52.222-35 | Dec 2001 | Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans |
| 52.222-36 | Jun 1998 | Affirmative Action for Workers with Disabilities |
| 52.222-37 | Dec 2001 | Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans |
| 52.223-6 | May 2001 | Drug-Free Workplace |
| 52.223-14 | Oct 2000 | Toxic Chemical Release Reporting |
| 52.225-1 | Feb 2000 | Buy American Act - Balance of Payments Program – Supplies |
| 52.225-13 | Jul 2000 | Restrictions on Certain Foreign Purchases |
| 52.227-1 | Jul 1995 | Authorization and Consent, Alternate I (Apr 1984) |
| 52.227-2 | Aug 1996 | Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000) |
| 52.227-11 | Jun 1997 | Patent Rights - Retention by the Contractor (Short Form) (NOTE: In accordance with FAR 27.303 (a) (2), paragraph (f) is modified to include the requirements in FAR 27.303 (a) (2) (i) through (iv). The frequency of reporting in (i) is annual. |
| 52.227-14 | Jun 1987 | Rights in Data – General |
| 52-232-9 | Apr 1984 | Limitation on Withholding of Payments |
| 52.232-17 | Jun 1996 | Interest (Over $100,000) |
| 52.232-20 | Apr 1984 | Limitation of Cost |
| 52.232-23 | Jan 1986 | Assignment of Claims |
| 52.232-25 | May 2001 | Prompt Payment |
| 52.232-34 | May 1999 | Payment by Electronic Funds Transfer--Other Than Central Contractor Registration |
| 52.233-1 | Dec 1998 | Disputes |
| 52.233-3 | Aug 1996 | Protest After Award |
| 52.242-1 | Apr 1984 | Notice of Intent to Disallow Costs |
| 52.242-3 | May 2001 | Penalties for Unallowable Costs (Over $500,000) |
| 52.242-4 | Jan 1997 | Certification of Final Indirect Costs |

| | | |
|---|---|---|
| 52.242-13 | Jul 1995 | Bankruptcy (Over $100,000) |
| 52.243-2 | Aug 1987 | Changes - Cost Reimbursement, Alternate V (Apr 1984) |
| 52.244-2 | Aug 1998 | Subcontracts, Alternate II (Aug 1998) *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B., Advance Understandings. |
| 52.244-5 | Dec 1996 | Competition in Subcontracting (Over $100,000) |
| 52.245-5 | Jan 1986 | Government Property (Cost-Reimbursement, Time and Material, or Labor Hour Contract) |
| 52.246-23 | Feb 1997 | Limitation of Liability (Over $100,000) |
| 52.249-6 | Sep 1996 | Termination (Cost-Reimbursement) |
| 52.249-14 | Apr 1984 | Excusable Delays |

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES

| HHSAR Clause No. | Date | Title |
|---|---|---|
| 352.202-1 | Jan 2001 | Definitions - with Alternate paragraph (h) (Jan 2001) |
| 352.228-7 | Dec 1991 | Insurance - Liability to Third Persons |
| 352.232-9 | Apr 1984 | Withholding of Contract Payments |
| 352.233-70 | Apr 1984 | Litigation and Claims |
| 352.242-71 | Apr 1984 | Final Decisions on Audit Findings |
| 352.270-5 | Apr 1984 | Key Personnel |
| 352.270-6 | Jul 1991 | Publication and Publicity |

[END OF GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT – Rev. 05/2001]

# PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

## SECTION J - LIST OF ATTACHMENTS

The following Attachments are provided in full text with this Solicitation:

**PACKAGING AND DELIVERY OF PROPOSALS (Attached to this listing)**

**HOW TO PREPARE AN ELECTRONIC PROPOSAL: (Attached to this listing)**

**PROPOSAL INTENT RESPONSE SHEET [SUBMIT ON/BEFORE: Feb. 25, 2002] (Attached to this listing)**

[NOTE: Your attention is directed to the "Proposal Intent Response Sheet". If you intend to submit a proposal, you must complete this form and return it to this office via fax or e-mail on or before the date identified above. The receipt of this form is critical as it contains information essential for CMB's coordination of the electronic submission and review of proposals.]

**RFP FORMS AND ATTACHMENTS:**

THE RFP FORMS/ATTACHMENTS LISTED BELOW ARE AVAILABLE IN A VARIETY OF FORMATS AND MAY BE VIEWED OR DOWNLOADED DIRECTLY FROM THIS SITE:

http://www.niaid.nih.gov/contract/ref.htm

## APPLICABLE TO TECHNICAL PROPOSAL (INCLUDE THESE DOCUMENTS/FORMS WITH YOUR TECHNICAL PROPOSAL):

- **Technical Proposal Cover Sheet**
- **Technical Proposal Cost Information**
- **Summary of Related Activities**
- **Government Notice for Handling Proposals**

## APPLICABLE TO BUSINESS PROPOSAL (INCLUDE WITH YOUR BUSINESS PROPOSAL):

- **NIH-2043, Proposal Summary and Data Record**
- **Small Business Subcontracting Plan Format**
- **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours**
- **Offeror's Points of Contact**

## TO BECOME CONTRACT ATTACHMENTS (INFORMATION ONLY):

- **NIH(RC)-4: Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts**
- **NIH(RC)-7: Procurement of Certain Equipment, (OMB Bulletin 81-16)**
- **Safety and Health, HHSAR Clause 352.223-70**
- **Privacy Act System of Records (09-25-0200)**
- **Report of Government Owned, Contractor Held Property**
- **Disclosure of Lobbying Activities, OMB Form LLL**

## PACKAGING/DELIVERY/ELECTRONIC SUBMISSION OF THE PROPOSAL

*Listed below are delivery instructions for the submission of both PAPER and ELECTRONIC COPIES of your proposal.*

*PAPER SUBMISSION: The paper copy is the official copy for recording timely receipt of proposals. You are required to submit one original paper copy of your proposal along with the number of extra copies required below.*

*ELECTRONIC SUBMISSION: In addition to the paper submission, you are required to submit your proposal electronically through the CRON (Contracts Review Online) in accordance with the instructions provided below. If you experience difficulty or are unable to transmit, you should submit your proposal on a CD-Rom or ZipDisk by an express delivery service. We can then upload your proposal into the electronic system. You must certify that both the original paper and electronic versions of the proposal are identical.*

*SUBMISSION OF PROPOSALS BY FACSIMILE IS NOT ACCEPTABLE.*

### Shipment and marking of paper copies shall be as indicated below:

**A. EXTERNAL PACKAGE MARKING:**

In addition to the address cited below, mark each package as follows:

**"RFP NO. NIH-NIAID-DAIT-02-23**
**TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"**

**B. NUMBER OF COPIES:**

The number of copies required of each part of your proposal are as specified below.

**Technical Proposal:** One (1) unbound signed original and three (3) unbound copies. Ten (10 copies of all material not available electronically (i.e. SOPs, Pertinent Manuals, Nonscannable Figures or Data, and Letters of Collaboration/Intent).

**Business Proposal:** One (1) unbound signed original and three (3) unbound copies.

**C. PAPER COPIES and CD-Rom or ZipDisk to:**

| If Hand Delivery or Express Service | If using U.S. Postal Service |
|---|---|
| Scott Drega<br>Contract Specialist<br>Contract Management Branch, DEA<br>NIAID, NIH<br>6700-B Rockledge Drive, Room 2230<br>Bethesda, Maryland 20817 | Scott Drega<br>Contract Specialist<br>Contract Management Branch, DEA<br>NIAID, NIH<br>6700-B Rockledge Drive, Room 2230, MSC 7612<br>Bethesda, Maryland 20892-7612 |

*NOTE: All material sent to this office by Federal Express should be sent to the Hand Carried Address.*

NOTE: The U.S. Postal Service's "Express Mail" does not deliver to the hand delivered (20817 zip code) address. Any package sent to this address via this service will be held at a local post office for pick-up. THE GOVERNMENT IS NOT RESPONSIBLE FOR PICKING UP ANY MAIL AT A LOCAL POST OFFICE. If a proposal is not received at the place, date, and time specified herein, it will be considered a "late proposal," in accordance with HHSAR 352.215-70, Late Proposals and Revisions (NOV 1986).

# HOW TO PREPARE AND SUBMIT AN ELECTRONIC PROPOSAL

**PAGE LIMITS -- THE NARRATIVE PORTION OF THE TECHNICAL PROPOSAL IS LIMITED TO NOT-TO-EXCEED ONE-HUNDRED (100) PAGES,** [INCLUDING: Appendices, Attachments, Operating Manuals, Non-Scannable Figures or Data, Letters of Intent, etc.] **WITH THE NARRATIVE OF THE TECHNICAL APPROACH PORTION OF THE PROPOSAL NOT-TO-EXCEED THIRTY-FIVE (35) PAGES.** ANY PORTIONS OF YOUR PROPOSAL NOT AVAILABLE ELECTRONICALLY ARE ALSO CONSIDERED TO BE INCLUDED IN THE TOTAL PAGE LIMITATION. PAGES IN EXCESS OF THIS LIMITATION WILL BE REMOVED FROM THE PROPOSAL AND WILL NOT BE READ OR EVALUATED.

**Note that although no page limit has been placed on the Business Proposal, offerors are encouraged to limit its content to only those documents necessary to provide adequate support for the proposed costs.**

**ELECTRONIC SUBMISSION** – To submit a proposal electronically under this RFP, offerors will need to prepare the proposal on a word processor or spreadsheet program (for the business portion) and convert them to Adobe Acrobat Portable Document Format (.pdf). THE TECHNICAL PROPOSAL AND BUSINESS PROPOSAL MUST BE CONTAINED ON SEPARATE FILES which must be identified as either TECHNICAL or BUSINESS and include some recognizable portion of the ORGANIZATION NAME.

Please note that the electronic submission does not replace the requirement to submit a signed, unbound original paper copy of both your Technical and Business Proposal, along with any required unbound duplicate copies. These paper originals should be mailed or hand-delivered to the address provided in this attachment and must be received on/before the closing date and time.

There is no limit to the size (MB) of the two electronic PDF files to be submitted; however, the size of the technical proposal is limited to the page limitation language outlined above. For purposes of assessing compliance with the page count, technical proposals will be viewed using the print function of the Adobe Acrobat Reader, Version 4.0 (or higher).

**Formatting Requirements:**

- Do not embed sound or video (e.g., MPEG) files into the proposal documents. The evaluation system does not have the capability to read these files.
- Keep graphics embedded in documents as simple as possible. Complex graphics require longer periods for the computers used in the evaluation system to draw, and redraw these figures and scrolling through the document is slowed significantly.
- Type density and size must be 10 to 12 points. If constant spacing is used, there should be no more than 15 cpi, whereas proportional spacing should provide an average of no more than 15 cpi. There must be no more than six lines of text within a vertical inch. Margins must be set to 1 inch around.
- Limit colors to 256 colors at 1024 x 768 resolution; avoid color gradients.
- Simplify the color palette used in creating figures.
- Be aware of how large these graphics files become. Large files are discouraged.
- Limit scanned images as much as possible.
- Limit appendices and attachments to relevant technical proposal information (e.g., SOPs, pertinent manuals, non-scannable figures or data, resumes, letters of commitment/intent).

**SUBMISSION OF "PROPOSAL INTENT TO RESPOND SHEET":**

Approximately TWO weeks prior to the due date of the proposals, all offerors who submitted a "Proposal Intent Response Sheet" will be provided with specific electronic access information and electronic proposal transmission instructions. For this reason, it is imperative that all offerors who are intending to submit a proposal in response to this RFP contact the Contract Specialist identified in this RFP and complete and submit the attached "Proposal Intent Response Sheet" by the date provided on that Attachment.

**CREATE ADOBE PDF ONLINE** -- Adobe will allow you to create 5 documents on a trial for free. If you want to use the site regularly it costs $10/month or $100/year. Please link to the following URL for information:

https://createpdf.adobe.com/index.pl/3847995518.39272?BP=IE

**LOG-IN / TRANSMISSION INSTRUCTIONS:**

1. Log-in Site: https://apps.niaid.nih.gov/ecms/cmsproposal/
2. Log-in Name: Will be provided by the Contract Specialist.
3. Log-in Password: Will be provided via telephone by the Contract Specialist after Log-in Name is provided.

4. Procedure -- When your proposal is completed and converted to a PDF file using Adobe Acrobat, it is ready to be transmitted electronically. You must upload separate Technical and Business Proposal Files. It is recommended that proposals be transmitted a few days before the due date so that you will have sufficient time to overcome any transmission difficulties.

- You must have Explorer 3.1 or higher.
- It is essential that you use antiviral software to scan all documents.
- Click on "Sign On" and enter your log-in name and password.
- Click on "Browse" to locate your saved files on your computer.
- Click on "Upload Proposal" after you have located the correct file.
- After a file is uploaded, a link to the file will appear under "Upload Files" at the bottom of the screen. Click on that link to view the uploaded file.
- If you experience difficulty in accessing your documents, please contact the appropriate NIH contracts office immediately.
- If you wish to revise your proposal before the closing date and time, simply log in again and re-post.

**USER ACCESS TO THE POSTING SITE WILL BE DENIED AFTER THE RFP CLOSING DATE AND TIME PROVIDED WITH THIS RFP OR ITS MOST RECENT AMENDMENT(S).**

# PROPOSAL INTENT RESPONSE SHEET

**RFP No.:** NIH-NIAID-DAIT-02-23
**RFP Title:** Statistical and Clinical Coordinating Center for Autoimmune Disease Clinical Trials (SACCC-ADCT)

Please review the attached Request for Proposal. Furnish the information requested below and return this page by **February 25, 2002**. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

**Since your proposal will be submitted electronically, please include the name and e-mail of the individual to whom the electronic proposal instructions, login code, and password should be provided.**

[ ] DO INTEND TO SUBMIT A PROPOSAL
[ ] DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:

**Company/Institution Name (print):** _____
**Address (print):** _____
_____
_____
_____

**Project Director's Name (print):** _____
**Title (print):** _____
**Signature/Date:** _____
**Telephone Number and E-mail Address (print clearly):**
_____
_____

***Name of individual to whom electronic proposal instructions should be sent:**

**Name:** _____
**Title:** _____
**E-Mail Address:** _____
**Telephone Number:** _____

**Names of Collaborating Institutions and Investigators (include Subcontractors and Consultants) (print):**
_____
_____
_____
_____
*(Continue list on a separate page if necessary)*

RETURN VIA FAX OR E-MAIL TO:
CMB, NIAID, NIH
Room 2230
6700-B Rockledge Drive, MSC 7612
Bethesda, MD 20892-7612
Attn: Scott Drega
RFP-NIH-NIAID-DAIT-02-23
FAX# (301)480-5253 or (301)402-0972
Email : Sdrega@niaid.nih.gov

# PART IV – REPRESENTATIONS AND INSTRUCTIONS

## SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

**Representations, Certifications, and Other Statements of Offerors or Quoters (Negotiated).**

1. REPRESENTATIONS AND CERTIFICATIONS

The Representations and Certifications required by this particular acquisition can be accessed electronically from the INTERNET at the following address:

http://rcb.nci.nih.gov/forms/rcneg.pdf

If you are unable to access this document electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

**IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLETE THE REPRESENTATIONS AND CERTIFICATIONS AND SUBMIT THEM AS PART OF YOUR BUSINESS PROPOSAL.**

# SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

**1.** GENERAL INFORMATION

a. **INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION** [FAR Clause 52.215-1 (May 2001)]

(a) *Definitions*. As used in this provision--

*Discussions* are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

"*In writing*", "writing", or "*written*" any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

"*Proposal modification*" is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

"*Proposal revision*" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

"*Time,*" if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) *Amendments to solicitations*. If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) *Submission, modification, revision, and withdrawal of proposals*. (1) Unless other methods (*e.g.*, electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show--

(i) The solicitation number;
(ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);
(iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;
(iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and
(v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) *Submission, modification, revision, and withdrawal of proposals*. (i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

(ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

*(1)* If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

*(2)* There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

*(3)* It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

(iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

(4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.

(5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.

(6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.

(7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.

(8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

(d) *Offer expiration date*. Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

**[Note: In accordance with HHSAR 352.215-1, the following paragraph (e) is substituted for the subparagraph (e) of the provision at FAR 52.215-1.]**

(e) *Restriction on disclosure and use of data*. (1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act,

5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. The legend reads:

> Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.
>
> The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.
>
> If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.
>
> The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

(2) In addition, the offeror should mark each page of data it wishes to restrict with the following statement:

> "Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

(3) Offerors are cautioned that proposals submitted with restrictive legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

(f) *Contract award*. (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

(2) The Government may reject any or all proposals if such action is in the Government's interest.

(3) The Government may waive informalities and minor irregularities in proposals received.

(4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

(5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.

(6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.

(7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.

(8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

(9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.

(10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.

(11) The Government may disclose the following information in postaward debriefings to other offerors:

(i) The overall evaluated cost or price and technical rating of the successful offeror;
(ii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;
(iii) A summary of the rationale for award; and
(iv) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

(End of Provision)

**Alternate I** (October 1997). As prescribed in 15.209(a)(1), substitute the following paragraph (f)(4) for paragraph (f)(4) of the basic provision:

(f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.

b. **NAICS CODE AND SIZE STANDARD**

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this RFP), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

(1) The North American Industry Classification System (NAICS) code for this acquisition is 541710 .
(2) The small business size standard is 500 employees .

**THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in every solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification System (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.**

c. **NOTICE OF PRICE EVALUATION ADJUSTMENT FOR SMALL DISADVANTAGED BUSINESS CONCERNS**

In accordance with FAR Clause 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns, incorporated in Section I.3., offerors will be evaluated by adding a factor of 10 percent to the price of all offers, except offers from small disadvantaged business concerns that have not waived the adjustment. (Note: A listing of other offerors who are excepted and will not have this evaluation factor added to their offer may be found in subparagraph (b) of FAR Clause 52.219-23.

A small disadvantaged business concern may elect to waive the adjustment, in which case the factor will be added to its offer for evaluation purposes. The agreements in paragraph (d) of FAR Clause 52.219-23 do not apply to offerors that waive the adjustment.

**AN OFFEROR WHO ELECTS TO WAIVE THIS EVALUATION ADJUSTMENT MUST SPECIFICALLY INDICATE WITH A STATEMENT TO THIS EFFECT ON THE COVER PAGE OF ITS BUSINESS PROPOSAL.**

d. **TYPE OF CONTRACT AND NUMBER OF AWARD(S)**

It is anticipated that ONE AWARD will be made from this solicitation and that the award will be made on/about September 16, 2002 .

It is anticipated that the award(s) from this solicitation will be a multiple-year, cost-reimbursement, completion type contract with a period of performance of seven (7) years, and that incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

e. **ESTIMATE OF EFFORT**

It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the effort to be approximately 18,720 labor hours (~ 9 FTEs) per year; a total of 131,040 total labor hours (~ 63 FTEs) over a 7-year period of performance. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

f. **COMMITMENT OF PUBLIC FUNDS**

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

g. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

h. **RELEASE OF INFORMATION**

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

i. **COMPARATIVE IMPORTANCE OF PROPOSALS**

You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The relative importance of the evaluation factors is specified in SECTION M of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

j. **PREPARATION COSTS**

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

k. **SERVICE OF PROTEST** (AUGUST 1996) - FAR 52.233-2

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accounting Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Brenda J. Velez
Contracting Officer
Contract Management Branch, DEA
National Institute of Allergy and Infectious Diseases
6700-B Rockledge Drive, Room 2230, MSC 7612
BETHESDA MD 20892-7612

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

(End of Provision)

l. **LATE PROPOSALS AND REVISIONS**, HHSAR 352.215-70

Notwithstanding the procedures contained in FAR 52.215-1(c)(3) of the provision of this solicitation entitled Instructions to Offerors—Competitive Acquisition, a proposal received after the date specified for receipt may be considered if it offers significant cost or technical advantages to the Government; and it was received before proposals were distributed for evaluation, or within five calendar days after the exact time specified for receipt, whichever is earlier.

(End of provision)

m. **USE OF INTERNET WEB SITE ADDRESSES (URLs) IN PROPOSALS**

Unless otherwise specified or required in NIAID solicitations, internet Web Site addresses (URLs) may not be used to provide information necessary to the conduct of the review of the proposal. Direct access to an internet site by a Reviewer who is examining and reviewing the proposal on behalf of the NIAID could compromise their anonymity during the review process. If a URL contains information pertinent to the proposal content, the offeror must provide access to the website via a temporary website portal which allow reviewers the capability to view and interact with the site.

The proposal must clearly identify the URLs to be accessed and the procedure for accessing the temporary website portal. Access must not require the identity of the individual.

## 2. INSTRUCTIONS TO OFFERORS

### a. GENERAL INSTRUCTIONS

**INTRODUCTION**

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

**Contract Type and General Clauses**

It is contemplated that a cost-reimbursement, completion type contract will be awarded. (See General Information) Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

(1) **Authorized Official and Submission of Proposal**

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

Include RFP title, number, name of organization, identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments.

(2) **Proposal Summary and Data Record (NIH-2043)**

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See Section J, Attachment entitled, PROPOSAL SUMMARY AND DATA RECORD).

(3) **Separation of Technical and Business Proposals**

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See Attachment entitled, TECHNICAL PROPOSAL COST INFORMATION/SUMMARY OF LABOR AND DIRECT COSTS).) However, the technical proposal should **not** include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any)., and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

(4) **Alternate Proposals**

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

(5) **Evaluation of Proposals**

The Government will evaluate technical proposals in accordance with the criteria set forth in PART IV, SECTION M of this RFP.

(6) **Potential Award Without Discussions**

The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.

(7) **Use of the Metric System of Measurement**

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

**Hard Metric** - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

**Soft Metric** - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

**Dual Systems** - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

(8) **Data and Safety Monitoring in Clinical Trials**

All offerors are directed to the full text of the NIH Policies regarding Data and Safety Monitoring and Reporting of Adverse Events that are found in the NIH Guide for Grants and Contracts Announcements at the following web sites:

http://grants.nih.gov/grants/guide/notice-files/not98-084.html
http://grants.nih.gov/grants/guide/notice-files/not99-107.html
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html

All offerors receiving an award under this solicitation must comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this solicitation.

The following is a brief summary of the Data and Safety Monitoring and Adverse Event Reporting Requirements:

Data and Safety Monitoring is required for every clinical trial. Monitoring must be performed on a regular basis and the conclusions of the monitoring reported to the Project Officer.

The type of data and safety monitoring required will vary based on the type of clinical trial and the potential risks, complexity and nature of the trial. A plan for data and safety monitoring is required for all clinical trials. Phase III clinical trials generally require the establishment of a Data Safety Monitoring Board (DSMB). The establishment of a DSMB is optional for Phase I and Phase II clinical trials.

The DSMB/Plan is established at the time the protocol is developed and must be approved by both the Institutional Review Board (IRB) and the Government and in place before the trial begins. If the protocol will be developed under the contract awarded from this solicitation, a general description of the data and safety monitoring plan must be submitted as part of the proposal and will be reviewed by the scientific review group (Technical Evaluation Panel, (TEP)) convened to evaluate the proposal. If the protocol is developed and is included as part of the submitted proposal, a complete and specific data and safety monitoring plan must be submitted as part of the proposal.

Monitoring Plans, at a minimum, must include the prompt reporting of adverse events to the IRB, FDA and NIH. The frequency of reporting of the conclusions of the monitoring activities should also be described in the plan. The overall elements of each plan may vary depending on the size and complexity of the trial. Examples of monitoring activities to be considered are described in the NIH Policy for Data and Safety Monitoring at http://grants.nih.gov/grants/guide/notice-files/not98-084.html

For multi-site Phase I and Phase II trials, a central reporting entity that will be responsible for preparing timely summary reports of adverse events for distribution among sites and IRBs should be considered.

Organizations with a large number of clinical trials may develop standard monitoring plans for Phase I and Phase II trials. In this case, such organizations may include the IRB-approved monitoring plan as part of the proposal submission.

(10) **Obtaining and Disseminating Biomedical Research Resources**

As a public sponsor of biomedical research, the National Institutes of Health (NIH) has a dual interest in accelerating scientific discovery and facilitating product development. Intellectual property restrictions can stifle the broad dissemination of new discoveries and limit future avenues of research and product development. At the same time, reasonable restrictions on the dissemination of research tools are sometimes necessary to protect legitimate proprietary interests and to preserve incentives for commercial development. To assist NIH contractors achieve an appropriate balance, the NIH has provided guidance in the form of a two-part document, consisting of Principles setting forth the fundamental concepts and Guidelines that provide specific information to patent and license professionals and sponsored research administrators for implementation.

The purpose of these Principles and Guidelines is to assist NIH funding recipients in determining: 1) Reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the public and private sectors (disseminating research tools); and 2) Restrictions to accept as a conditions of receiving access to research tools for use in NIH-funded research (acquiring research tools). The intent is to help recipients ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

This policy, entitled, "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090] will be included in any contract awarded from this solicitation. It can be found at the following website: http://ott.od.nih.gov/NewPages/64FR72090.pdf.

(11) **Privacy Act (Treatment of Proposal Information)**

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:

- to the cognizant audit agency and the General Accounting Office for auditing.
- to the Department of Justice as required for litigation.
- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

(12) **Selection of Offerors**

a) The acceptability of the scientific and technical portion of each research contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.

b) The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.

c) If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.

d) If the Government intends to conduct discussions prior to awarding a contract-

(1) Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.

(2) The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all offerors in the competitive range.

While it is this Institute's policy to conduct discussions with all offerors in the competitive range, the Institute reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected sources in accordance with HHSAR 315.370.

e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.

f) The Institute reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet the Institute's requirements. Synopses of awards exceeding $25,000 will be published in the Commerce Business Daily and FedBizOpps.

(13) **Small Business Subcontracting Plan**

If the proposed contract exceeds a total estimated cost of $500,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, SECTION J, List of Attachments, is an example of such a plan.

a) THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.

b) The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.

c) The offeror understands that:

(1) No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.

(2) An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HubZone Small Businesses, and Veteran-Owned Small Businesses to participate in the performance of the contract.

(3) If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.

(4) Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.

(5) It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HubZone Small Business Concerns, and Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.

(6) The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.

d) Each plan must contain the following:

(1) Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, and Veteran-Owned Small Business Concerns as subcontractors.

(2) A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, and Veteran-Owned Small Businesses.

(3) A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, and/or Veteran-Owned Small Business Concerns.

(4) A description of the method used to develop the subcontracting goals.

(5) A description of the method used to identify potential sources for solicitation purposes.

(6) A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, and Veteran-Owned Small Businesses.

(7) The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.

(8) A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, and Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.

(9) Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of $500,000 adopt a plan similar to the plan agreed upon by the offeror.

(10) Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (SF 294 and SF 295) to the Government.

(11) List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, and Veteran-Owned Small Businesses and award subcontracts to them.

For additional information about each of the above elements required to be contained the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan, and the Sample Subcontracting Plan which is provided as an attachment to this RFP in SECTION J.

(14) **HUBZone Small Business Concerns**

Small Business offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS, which is incorporated by reference in ARTICLE I.3. of this solicitation. Qualified HUBZone firms are identified in the Small Business Administration website at http://www.sba.gov/hubzone.

(15) **Extent of Small Disadvantaged Business Participation**

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Industry Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed $500,000 ($1,000,000 for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

The factor entitled “Extent of Small Disadvantaged Business Participation” as set forth under the Evaluation Criteria in Section M shall be used for evaluation purposes. Credit under this evaluation factor is not available to SDB concerns that receive a Price Evaluation Adjustment (PEA) under FAR 19.11. Therefore, an SDB will be evaluated on this factor only if that SDB concern waives the PEA. **Waiver of the price evaluation adjustment shall be clearly stated in the proposal.**

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) codes, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). The NAICS codes can be found at: http://www.sba.gov/size

The Department of Commerce website for the annual determination is:
http://www.arnet.gov/References/sdbadjustments.htm

Offerors shall include with their offers, SDB targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS Industry Subsector(s). The applicable authorized NAICS Industry Subsector(s) for this project is (are) identified elsewhere in this RFP. A total target for SDB participation by the prime contractor, that includes any joint ventures and team members, shall be provided as well as a total target for SDB participation by subcontractors. In addition, offerors must provide information that describes their plans for meeting the targets set forth in their proposal. **This information shall be provided in one clearly marked section of the Business Proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.**

If the evaluation factor in this solicitation includes an SDB evaluation factor or subfactor that considers the extent to which SDB concerns are specifically identified, the SDB concerns considered in the evaluation shall be listed in any resultant contract. Offerors should note that addressing the extent of small disadvantaged business participation **is not in any way intended to be a substitute** for submission of the subcontracting plan, if it is required by this solicitation. An example of the type of information that might be given (in addition to the narrative describing the plan for meeting the targets) follows:

EXAMPLE

Targets for SDB Participation - NAICS Industry Subsector 223

| | **SDB Percentage of Total Contract Value** | **SDB Dollars** |
|---|---|---|
| Total Contract Value- $1,000,000 | 25% | $250,000 |
| SDB Participation by Prime | 10% | $100,000 |
| (Includes joint venture partners and team arrangements)* | | |
| SDB Participation by subcontractors | 15% | $150,000 |

***NOTE:** FAR Subpart 9.6 defines "Contractor team arrangements" to include two or more companies forming a partnership or joint venture to act as a potential prime contractor, or a potential prime contractor who agrees with one or more companies to have them act as its subcontractors on a specific contract or acquisition program. For purposes of evaluation of the SDB participation factor, FAR 19.1202-4 requires that SDB joint ventures and teaming arrangements at the prime level be presented separately from SDB participation by subcontractors.

(16) **Reimbursement of Costs for Independent Research and Development Projects** (Commercial Organizations Only)

The primary purpose of the Public Health Service (PHS) is to support and advance independent research within the scientific community. This support is provided in the form of contracts and grants totaling approximately 7 billion dollars annually. PHS has established effective, time tested and well recognized and accepted procedures for stimulating and supporting this independent research by selecting from multitudes of proposals those research projects most worthy of support within the constraints of its appropriations. The reimbursement of independent research and development costs not incidental to product improvement, through the indirect cost mechanism, would circumvent this competitive process.

To ensure that all research and development projects receive similar and equal consideration, all offerors may compete for direct funding for independent research and development projects they consider worthy of support by submitting those projects to the appropriate Public Health Service grant and/or contract office for review. Since these projects may be submitted for direct funding, the successful offeror agrees that no costs for any independent research and development project, including applicable indirect costs, will be claimed under any contract resulting from this solicitation.

(17) **Salary Rate Limitation in Fiscal Year 2002** **

Offerors are advised that pursuant to P.L.___*___, no NIH Fiscal Year 2002 (October 1, 2001 - September 30, 2002) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patent care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor.).

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I*. The salary rate limitation set by P.L. ___*___ applies only to Fiscal Year 2002 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I* annual salary rate limit also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. ___*___ states in pertinent part:

> "None of the funds appropriated in this Act for the National Institutes of Health and the Substance Abuse, and Mental Health Services Administration shall be used to pay the salary of an individual through a grant or extramural mechanism at a rate in excess of Executive Level I."

***FY-2002 information is pending passage of legislation. Information regarding the FY02001 rate can be found at: http://www.opm.gov/oca/01tables/execses/html/01execsc.htm.**

(18) **Institutional Responsibility Regarding Conflicting Interests of Investigators**

**EACH INSTITUTION MUST:**

(a) Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.

(b) Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.

(c) Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

(d) Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

(e) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and (2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.

(f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

(g) Certify, in each application/proposal for funding to which the regulations applies, that:

1) there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;

2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;

3) the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and

4) the Institution will otherwise comply with the regulations.

**Institutional Management Of Conflicting Interests**

(a) The designated official(s) must: (1) review all financial disclosures; and (2) determine whether conflict of interest exists, and if so, determine what actions should be taken by the Institution to manage, reduce or eliminate such conflict of interest. **A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research**.

Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:

(i) public disclosure of significant financial interests;
(ii) monitoring of research by independent reviewers;
(iii) modification of the research plan;
(iv) disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
(v) divestiture of significant financial interests; or
(vi) severance of relationships that create actual or potential conflicts of interests.

(b) An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (a) of this section, as the Institution deems appropriate.

(19) **Electronic and Information Technology Accessibility**

Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by P.L.105-220 under Title IV (Rehabilitation Act Amendments of 1998) and the Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards (36 CFR part 1194) require that all EIT acquired must ensure that:

1. Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities; and

2. Members of the public with disabilities seeking information or services from an agency have access to and use of information and data that is comparable to the access to and use of information and data by members of the public who are not individuals with disabilities.

This requirement includes the development, maintenance, and/or use of EIT products/services, therefore, any proposal submitted in response to this solicitation must demonstrate compliance with the established EIT Accessibility Standards.

Further information about Section 508 is available via the Internet at http://www.section508.gov .

(20) **Solicitation Provisions Incorporated by Reference**, FAR 52.252-1 (February 1998)

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: http://www.arnet.gov/far/.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

a) Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).

b) Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).

c) Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).

b. **TECHNICAL PROPOSAL INSTRUCTIONS**

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

(1) **Technical Discussions**

The technical discussion included in the technical proposal should respond to the items set forth below:

a) **Statement of Work**

(1) Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

(2) Approach

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

(3) Methods

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

(4) Schedule

Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

b) **Personnel**

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

**OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.**

(1) Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

(2) Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

(3) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

- The specific items or expertise they will provide.
- Their availability to the project and the amount of time anticipated.
- Willingness to act as a consultant.
- How rights to publications and patents will be handled.

(4) Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

(2) **Technical Evaluation**

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in the Technical Evaluation Criteria (SEE SECTION M).

(3) **Additional Technical Proposal Information**

a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.

b) The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

(4) **Other Considerations**

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

a) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.

b) Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.

c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.

d) Other factors you feel are important and support your proposed research.

e) Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

(5) **Information Technology Systems Security**

If this project involves Information Technology, the proposal must present a detailed outline of its proposed Information Technology systems security program which complies with the requirements of the Statement of Work, the Computer Security Act of 1987 Office of Management and Budget (OMB) Circular A-130, Appendix III, "Security of Federal Automated Information Systems," and the DHHS Automated Information Systems Security Program Handbook (Release 2.0, dated May, 1994). The proposal will also need to include similar information for any subcontract proposed.

NOTE: OMB A-130 is accessible via web site: http://www.whitehouse.gov/WH/EOP/OMB/html/circular.html

c. **BUSINESS PROPOSAL INSTRUCTIONS**

(1) Basic Cost/Price Information

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

(2) Cost and Pricing Data

1. **General Instructions**

A. You must provide the following information on the first page of your pricing proposal:

(1) Solicitation, contract, and/or modification number;
(2) Name and address of offeror;
(3) Name and telephone number of point of contact;
(4) Name of contract administration office (if available);
(5) Type of contract action (that is, new contract, change order, price revision/redetermination, letter contract, unpriced order, or other);
(6) Proposed cost; profit or fee; and total;
(7) Whether you will require the use of Government property in the performance of the contract, and, if so, what property;
(8) Whether your organization is subject to cost accounting standards; whether your organization has submitted a CASB Disclosure Statement, and if it has been determined adequate; whether you have been notified that you are or may be in noncompliance with your Disclosure Statement or CAS, and, if yes, an explanation; whether any aspect of this proposal is inconsistent with your disclosed practices or applicable CAS, and, if so, an explanation; and whether the proposal is consistent with your established estimating and accounting principles and procedures and FAR Part 31, Cost Principles, and, if not, an explanation;
(9) The following statement: This proposal reflects our estimates and/or actual costs as of this date and conforms with the instructions in FAR 15.403-5(b)(1) and Table 15-2. By submitting this proposal, we grant the Contracting Officer and authorized representative(s) the right to examine, at any time before award, those records, which include books, documents, accounting procedures and practices, and other data, regardless of type and form or whether such supporting information is specifically referenced or included in the proposal as the basis for pricing, that will permit an adequate evaluation of the proposed price;
(10) Date of submission; and
(11) Name, title and signature of authorized representative.

B. In submitting your proposal, you must include an index, appropriately referenced, of all the cost or pricing data and information accompanying or identified in the proposal. In addition, you must annotate any future additions and/or revisions, up to the date of agreement on price, or an earlier date agreed upon by the parties, on a supplemental index.

C. As part of the specific information required, you must submit, with your proposal, cost or pricing data (that is, data that are verifiable and factual and otherwise as defined at FAR 15.401). You must clearly identify on your cover sheet that cost or pricing data are included as part of the proposal. In addition, you must submit with your proposal any information reasonably required to explain your estimating process, including--

(1) The judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data; and
(2) The nature and amount of any contingencies included in the proposed price.

D. You must show the relationship between contract line item prices and the total contract price. You must attach cost-element breakdowns for each proposed line item, using the appropriate format prescribed in the "Formats for Submission of Line Item Summaries" section of this table. You must furnish supporting breakdowns for each cost element, consistent with your cost accounting system.

E. When more than one contract line item is proposed, you must also provide summary total amounts covering all line items for each element of cost.

F. Whenever you have incurred costs for work performed before submission of a proposal, you must identify those costs in your cost/price proposal.

G. If you have reached an agreement with Government representatives on use of forward pricing rates/factors, identify the agreement, include a copy, and describe its nature.

H. As soon as practicable after final agreement on price or an earlier date agreed to by the parties, but before the award resulting from the proposal, you must, under the conditions stated in FAR 15.406-2, submit a Certificate of Current Cost or Pricing Data.

2. **Cost Elements**

Depending on your system, you must provide breakdowns for the following basic cost elements, as applicable:

A. **Materials and services**. Provide a consolidated priced summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.). Include raw materials, parts, components, assemblies, and services to be produced or performed by others. For all items proposed, identify the item and show the source, quantity, and price. Conduct price analyses of all subcontractor proposals. Conduct cost analyses for all subcontracts when cost or pricing data are submitted by the subcontractor. Include these analyses as part of your own cost or pricing data submissions for subcontracts expected to exceed the appropriate threshold in FAR 15.403-4. Submit the subcontractor cost or pricing data as part of your own cost or pricing data as required in paragraph 2.A.(2) of this table. These requirements also apply to all subcontractors if required to submit cost or pricing data.

(1) *Adequate Price Competition*. Provide data showing the degree of competition and the basis for establishing the source and reasonableness of price for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding, or expected to exceed, the appropriate threshold set forth at FAR 15.403-4 priced on the basis of adequate price competition. For interorganizational transfers priced at other than the cost of comparable competitive commercial work of the division, subsidiary, or affiliate of the contractor, explain the pricing method (see FAR 31.205-26(e)).

(2) *All Other*. Obtain cost or pricing data from prospective sources for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding the threshold set forth in FAR 15.403-4 and not otherwise exempt, in accordance with FAR 15.403-1(b) (i.e., adequate price competition, commercial items, prices set by law or regulation or waiver). Also provide data showing the basis for establishing source and reasonableness of price. In addition, provide a summary of your cost analysis and a copy of cost or pricing data submitted by the prospective source in support of each subcontract, or purchase order that is the lower of either $10,000,000 or more, or both more than the pertinent cost or pricing data threshold and more than 10 percent of the prime contractor's proposed price. The Contracting Officer may require you to submit cost or pricing data in support of proposals in lower amounts. Subcontractor cost or pricing data must be accurate, complete and current as of the date of final price agreement, or an earlier date agreed upon by the parties, given on the prime contractor's Certificate of Current Cost or Pricing Data. The prime contractor is responsible for updating a prospective subcontractor's data. For standard commercial items fabricated by the offeror that are generally stocked in inventory, provide a separate cost breakdown, if priced based on cost. For interorganizational transfers priced at cost, provide a separate breakdown of cost elements. Analyze the cost or pricing data and submit the results of your analysis of the prospective source's proposal. When submission of a prospective source's cost or pricing data is required as described in this paragraph, it must be included along with your own cost or pricing data submission, as part of your own cost or pricing data. You must also submit any other cost or pricing data obtained from a

subcontractor, either actually or by specific identification, along with the results of any analysis performed on that data.

B. **Direct Labor**. Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category, and furnish bases for estimates.

C. **Indirect Costs**. Indicate how you have computed and applied your indirect costs, including cost breakdowns. Show trends and budgetary data to provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation.

D. **Other Costs**. List all other costs not otherwise included in the categories described above (e.g., special tooling, travel, computer and consultant services, preservation, packaging and packing, spoilage and rework, and Federal excise tax on finished articles) and provide bases for pricing.

E. **Royalties**. If royalties exceed $1,500, you must provide the following information on a separate page for each separate royalty or license fee:

(1) Name and address of licensor.
(2) Date of license agreement.
(3) Patent numbers.
(4) Patent application serial numbers, or other basis on which the royalty is payable.
(5) Brief description (including any part or model numbers of each contract item or component on which the royalty is payable).
(6) Percentage or dollar rate of royalty per unit.
(7) Unit price of contract item.
(8) Number of units.
(9) Total dollar amount of royalties.
(10) If specifically requested by the Contracting Officer, a copy of the current license agreement and identification of applicable claims of specific patents (see FAR 27.204 and 31.205-37).

F. **Facilities Capital Cost of Money**. When you elect to claim facilities capital cost of money as an allowable cost, you must submit Form CASB-CMF and show the calculation of the proposed amount (see FAR 31.205-10).

3. **Formats for Submission of Line Item Summaries**

The detailed breakdown shall be in the format as shown on the form **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours** (SECTION J, List of Attachments). For each separate cost estimate, the offeror must furnish a breakdown by cost element as indicated above. In addition, summary total amounts shall be furnished. In the event the RFP cites specific line items, by number, a cost breakdown for each line item must be furnished.

To assist in the preparation of future cost estimates, the Projected Consumer Price Index may be accessed at: http://amb.nci.nih.gov/cpi.htm

4. There is a clear distinction between submitting cost or pricing data and merely making available books, records, and other documents without identification. The requirement for submission of cost or pricing data is met when all accurate cost or pricing data reasonably available to the offeror have been submitted, either actually or by specific identification, to the Contracting Officer or an authorized representative. As later information comes into your possession, it should be submitted promptly to the Contracting Officer in a manner that clearly shows how the information relates to the offeror's price proposal. The requirement for submission of cost or pricing data continues up to the time of agreement on price, or an earlier date agreed upon between the parties if applicable.

5. By submitting your proposal, you grant the Contracting Officer or an authorized representative the right to examine records that formed the basis for the pricing proposal. That examination can take place at any time before award. It may include those books, records, documents, and other types of factual information (regardless of form or whether the information is specifically referenced or included in the proposal as the basis for pricing) that will permit an adequate evaluation of the proposed price.

(3) Qualifications of the Offeror

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

a) **General Experience**

**General experience** is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

b) **Organizational Experience Related to the RFP**

**Organizational experience** is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

c) **Performance History**

**Performance history** is defined as meeting contract objectives within **delivery** and **cost schedules** on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

d) **Pertinent Contracts**

**Pertinent contracts** is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

e) **Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

(4) Other Administrative Data

a) **Property**

(1) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the Contracting Officer. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes:

(a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.

(b) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.

(2) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.

(3) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractors Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

b) **Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38** (MAY 1999)

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232-34, Payment by Electronic Funds Transfer--Other than Central Contractor Registration.

(1) The solicitation number (or other procurement identification number).
(2) The offeror's name and remittance address, as stated in the offer.
(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
(4) The name, address, and 9-digit Routing Transit Number of the offeror's financial agent.
(5) The offeror's account number and the type of account (checking, savings, or lockbox).
(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

c) **Financial Capacity**

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

d) **Incremental Funding**

An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the contract are not available at the time of the contract award. If this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provisions are applicable:

**HHSAR 352.232-75, Incremental Funding (January 2001)**

(a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. Additional funds are intended to be allotted to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.

(b) The Limitation of Funds clause to be included in the resultant contract shall supersede the Limitation of Cost clause found in the General Provisions.

(End of provision)

e) **Facilities Capital Cost of Money, FAR 52.215-16, (October 1997)**

(This is applicable if you are a commercial organization.)

(a) Facilities capital cost of money [(see FAR 15.408(h)] will be an allowable cost under the contemplated contract, if the criteria for allowability in subparagraph 31.205-10(a)(2) of the Federal Acquisition Regulation are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

(b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision)

If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by checking the appropriate box below.

**[ ]** The prospective Contractor has specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).

**[ ]** The prospective Contractor has not specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

(5) Subcontractors

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

a) Willingness to perform as a subcontractor for specific duties (list duties).

b) What priority the work will be given and how it will relate to other work.

c) The amount of time and facilities available to this project.

d) Information on their cognizant field audit offices.

e) How rights to publications and patents are to be handled.

f) A complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:

http://ocm.od.nih.gov/contracts/rfps/FDP/PDPclausecover.htm

(6) Proposer's Annual Financial Report

A copy of the organization's most recent annual report must be submitted as part of the business proposal.

(7) Representations and Certifications

One copy of the Representations and Certifications attached as Section K shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of the Representations and Certifications shall be submitted from any proposed subcontractor.

(8) Travel Costs/Travel Policy

a) **Travel Costs - Commercial**

Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

b) **Travel Policy**

One copy of the offeror's (and any proposed subcontractor's) written travel policy shall be included in the business proposal (original only). If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

# SECTION M - EVALUATION FACTORS FOR AWARD

## 1. GENERAL

The major evaluation factors for this solicitation include technical (which encompasses experience and past performance factors) cost/price factors and Small Disadvantaged Business (SDB) Participation. Although technical factors are of paramount consideration in the award of the contract, cost/price and SDB participation is also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. In any case, the Government reserves the right to make an award(s) to that offeror whose proposal provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be carefully evaluated. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

## 2. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

SDB participation will not be scored, but the Government's conclusions about overall commitment and realism of the offeror's SDB Participation targets will be used in determining the relative merits of the offeror's proposal and in selecting the offeror whose proposal is considered to offer the best value to the Government.

The extent of the offeror's Small Disadvantaged Business Participation Targets will be evaluated before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of the information presented in the offeror's proposal. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

Offers will be evaluated on the following sub-factors:

(a) Extent to which SDB concerns are specifically identified
(b) Extent of commitment to use SDB concerns
(c) Complexity and variety of the work SDB concerns are to perform
(d) Realism of the proposal
(e) Past performance of offerors in complying with subcontracting plan goals for SDB concerns and monetary targets for SDB participation
(f) Extent of participation of SDB concerns in terms of the value of the total acquisition.

## 3. TECHNICAL EVALUATION CRITERIA

The technical evaluation committee uses the evaluation criteria when reviewing the technical proposals. Proposals will be judged solely on the written material provided by the Offeror. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

### A. TECHNICAL APPROACH **Points: 40**

1) Soundness and practicality of the technical approach for executing the requirements specified in the Work Statement, with adequate explanation, substantiation and justification for methods for handling the projected needs of the Autoimmunity Centers of Excellence (ACEs) and the Autoimmune Diseases Transplantation Consortium, including alternative strategies, for:

   a) providing statistical leadership for the design and analysis of clinical trials and mechanistic studies conducted by the ACE and the Consortium

   b) providing clinical trial expertise for the design, implementation, refinement, modification and monitoring of clinical trials and mechanistic studies conducted by the Consortium;

   c) establishing and administering reliable, efficient and responsive data management and quality assurance systems;

   d) designing and implementing clinical site monitoring and training requirements;

   e) providing support for regulatory functions and requirements associated with Investigational New Drug (IND) applications and Investigational Device Exemption (IDE) applications and clinical trials of experimental therapies

   f) establishing and managing systems for distribution and quality control of study products;

   g) providing statistical, technical, administrative and logistical support for the activities of the ACE and the Consortium and the NIAID Data and Safety Monitoring Boards (DSMB).

2) Understanding of the scope and objectives of the contract, recognition of potential difficulties that may arise in performing the work required, presentation of adequate solutions and understanding of the close coordination necessary between the NIAID, the ACEs Steering Committee, and the Consortium Operations Committee, the clinical sites and other site personnel.

### B. QUALIFICATIONS, EXPERIENCE AND AVAILABILITY OF PERSONNEL **Points: 30**

1) Principal Investigator/Co-investigators

   a) Proposed scientific, regulatory, technical and administrative leadership of the SACCC. This shall include the documented training, expertise, relevant experience, leadership/management skills and availability of the Principal Investigator and the surrounding leadership of the SACCC to successfully plan and manage the project.

   b) Expertise in autoimmune disease and transplantation specific clinical trial design, including documented training, clinical trial design expertise, relevant experience, leadership skills, and autoimmune disease specific medical expertise.

   c) Documented expertise in the implementation and monitoring of clinical trials, including clinical site training.

   d) Documented managerial ability to achieve delivery or performance requirements as demonstrated by the proposed use of management and other personnel resources and to successfully manage the project, including subcontractor and/or consultant efforts, if applicable, as evidenced by the management plan and demonstrated by previous relevant experience.

2) Other Personnel

Documented availability, training, qualifications, expertise, relevant experience, education and competence of the scientific, clinical, technical and administrative staff and any other proposed personnel [including proposed subcontractors and consultants], to perform the requirements of the work statement as evidenced by resumes, endorsements and explanations of previous efforts.

3) Staffing Plan

Staffing plan for the conduct of the project, including the appropriateness of the time commitments of all staff, the clarity and appropriateness of assigned roles, lines of authority.

4) Administrative and Organizational Framework

Adequacy of the administrative and organizational framework, with lines of authority and responsibility clearly demonstrated, and adequacy of the work plan, with proposed time schedule for achieving contract objectives and maintaining quality control over the implementation and operation of the project. Adequacy of back-up staffing and the evidence that they will be able to function as a team.

**C. EXPERIENCE AND CAPABILITIES OF THE ORGANIZATION** **Points: 20**

1) Documented relevant experience of the organization in managing projects of similar complexity and scope.

2) Clarity and appropriateness of lines of communication and authority for coordination and management of the project. Adequacy and feasibility of plans to ensure successful coordination of a multi-organizational collaboration.

3) Adequacy and feasibility of provisions for transitions involving predecessor and successor contractors.

**D. FACILITIES AND RESOURCES** **Points: 10**

Documented availability and adequacy of facilities, equipment and resources necessary to carry out the work statement.

**TOTAL POINTS: 100**